DOCKET

SUPREME COURT
OF THE UNITED STATES

No. 12-1128
Title: Medtronic, Inc., Petitioner
v.
Mirowski Family Ventures, LLC
Docketed: March 18, 2013
Lower Ct: United States Court of Appeals for the Federal Circuit
Case Nos.: (2011-1313, 2011-1372)
Decision Date: September 18, 2012
Rehearing Denied: December 14, 2012
Questions Presented

---Date---	--------Proceedings and Orders----------------------
Mar 14 2013	Petition for a writ of certiorari filed. (Response due April 17, 2013)
Apr 5 2013	Brief of respondent Mirowski Family Ventures, LLC in opposition filed.
Apr 25 2013	Reply of petitioner Medtronic, Inc. filed.
Apr 30 2013	DISTRIBUTED for Conference of May 16, 2013.
May 20 2013	Petition GRANTED.
Jun 5 2013	The time to file the joint appendix and petitioner's brief on the merits is extended to and including July 26, 2013.
Jun 5 2013	The time to file respondents' brief on the merits is extended to and including September 16, 2013.
Jul 26 2013	Joint appendix filed. (Statement of costs filed.)
Jul 26 2013	Brief of petitioner Medtronic, Inc. filed.
Aug 2 2013	Brief amicus curiae of the United States filed.
Aug 2 2013	Brief amici curiae of Legal Scholars filed.
Aug 2 2013	Brief amicus curiae of Tessera Technologies, Inc. in support of neither party filed.
Aug 19 2013	CIRCULATED.
Aug 20 2013	SET FOR ARGUMENT on Tuesday, November 5, 2013.
Sep 3 2013	Record from U.S.C.A. for Federal Circuit is electronic (Not PACER).
Sep 3 2013	Additional record received from U.S.C.A. for Federal Circuit. (1 box)
Sep 11 2013	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
Sep 16 2013	Brief of respondent Mirowski Family Ventures, LLC filed. (Distributed)
Sep 20 2013	Motion of Tessera Technologies, Inc. in support of neither party for leave to participate in oral argument as amicus curiae and for enlarged argument or, in

	the alternative divided argument filed
Sep 20 2013	Brief amicus curiae of Koninklijke Philips N V filed (Distributed)
Sep 23 2013	Brief amicus curiae of Intellectual Property Owners Association filed (Distributed)
Sep 30 2013	Joint opposition of the parties to motion of Tessera Technologies Inc for leave to participate in oral argument as amicus curiae and for divided argument
Oct 15 2013	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED
Oct 15 2013	Motion of Tessera Technologies Inc in support of neither party for leave to participate in oral argument as amicus curiae and for divided argument DENIED
Oct 16 2013	Reply of petitioner Medtronic Inc filed (Distributed)
Nov 5 2013	Argued For petitioner Seth P Waxman Washington D C and Curtis E Gannon Assistant to the Solicitor General Department of Justice Washington D C (for United States as amicus curiae) For respondents Arthur I Neustadt Alexandria Va
Jan 22 2014	Judgment REVERSED and case REMANDED Breyer J delivered the opinion for a unanimous Court
Jan 31 2014	Record for U S C A for the Federal Circuit has been RETURNED

PETITION
FOR
WRIT OF
CERTIORARI

12-1128

Supreme Court, U.S.
FILED
MAR 14 2013
OFFICE OF THE CLERK

No. 12-_____

IN THE
Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, AND MIROWSKI FAMILY VENTURES, LLC,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

Martin R. Lueck
Counsel of Record
Jan M. Conlin
Stacie E. Oberts
Robins, Kaplan, Miller & Ciresi LLP
2800 LaSalle Plaza
800 LaSalle Ave.
Minneapolis, MN 55402
(612) 349-8500

Mark C. Fleming
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Attorneys for Petitioner

March 14, 2013

QUESTION PRESENTED

In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007), this Court ruled that a patent licensee that believes that its products do not infringe the patent and accordingly are not subject to royalty payments is "not required ... to break or terminate its ... license agreement before seeking a declaratory judgment in federal court that the underlying patent is ... not infringed."

The question presented is whether, in such a declaratory judgment action brought by a licensee under *MedImmune*, the licensee has the burden to prove that its products do *not* infringe the patent, or whether (as is the case in all other patent litigation, including other declaratory judgment actions), the patentee must prove infringement.

PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT

There are no parties to the proceedings other than those listed in the caption.

Petitioner Medtronic, Inc. has no parent corporations and no publicly held company owns 10% or more of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Medtronic, Inc. ("Medtronic") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-18a) is reported at 695 F.3d 1266. The order of the court of appeals denying rehearing and rehearing *en banc* (App. 84a) is unreported. The opinion of the United States District Court for the District of Delaware (App. 19a-83a) is reported at 777 F. Supp. 2d 750.

JURISDICTION

The Federal Circuit entered judgment on September 18, 2012 and denied rehearing on December 14, 2012. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

35 U.S.C. § 281: "A patentee shall have remedy by civil action for infringement of his patent."

28 U.S.C. § 2201(a):

> In a case of actual controversy within its jurisdiction ... any court of the

> United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall the force and effect of a final judgment or decree and shall be reviewable as such.

INTRODUCTION

In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), this Court confirmed that a patent licensee that believes that its licensor is improperly demanding royalties for noninfringing products is not required to breach the license and risk infringement litigation, but may instead bring a declaratory judgment action asserting that "the agreement does not call for royalties because their product does not infringe the patent." *Id.* at 135. After Respondents asserted that certain of Medtronic's products were subject to the parties' license, Medtronic filed just such an action, while continuing to pay royalties under protest in a set aside account.

The Federal Circuit, however, significantly undermined the value of such an action by adopting a novel requirement that, in a declaratory judgment action under *MedImmune*, the accused infringer bears the burden of proving that its products *do not* infringe the patent. The court reached this conclusion while recognizing that, in traditional infringement litigation—whether a coercive claim by a patentee or a declaratory judgment claim by an accused infringer—the patentee has the burden of proving infringement and bears the risk of any failure of proof.

The Federal Circuit's unprecedented ruling is contrary to the settled principle that infringement must "be shown by satisfactory proof; it cannot be presumed." *R.R. Co. v. Mellon*, 104 U.S. 112, 119 (1881). Nor does the procedural realignment of parties in a declaratory judgment action reallocate the burden of proof—a principle the Federal Circuit acknowledged. App. 10a. The Federal Circuit's conclusion that the presence of a patent license justified a fundamental departure from these principles is unsupported and deserves this Court's review.

If not reversed, the Federal Circuit's decision will have numerous undesirable consequences. First and foremost, it dramatically undercuts the holdings in *MedImmune* and the remedies it provided. Under the Federal Circuit's new regime, a declaratory judgment under *MedImmune* comes with a significant price: the duty to prove the *negative* proposition that the involved products do *not* infringe—a formidable task where, as here, the asserted patents include hundreds of individual claims and liability could rest on any one of several infringement theories. The only way a licensee could ensure that the burden of proof remains with the patentee would be to repudiate the license and invite the patentee to sue for infringement, thereby "risk[ing] such serious consequences" as treble damages and attorney's fees—the very outcome the Court allowed licensees to avoid in *MedImmune*. 549 U.S. at 122.

The Federal Circuit's decision also effectively allows patentees to trigger a judicial presumption of infringement simply by *asserting* to their licensees that particular products are covered by the licensed patents. Such a doctrine is unsupported by anything in *MedImmune*, the Declaratory Judgment Act, the Patent Act, or this Court's patent jurisprudence. There is certainly no basis to conclude that, simply because parties sign a license agreeing to royalty payments for infringing products, the patentee's assertion that certain newly-developed products infringe should be taken as correct unless the licensee proves otherwise. Rather, the risk of nonpersuasion on the patentee's claim of infringement should be allocated identically, regardless of whether the patentee claims that the infringement is to be compensated by a royalty found by a jury (in the case of a coercive litigation) or a royalty previously determined by the parties' license agreement (in the case of a *MedImmune*-type declaratory judgment).

Here, Respondents accused products first marketed in 2004 of infringing patent claims first issued in 2003 and 2007, over a decade after the license was signed in 1991. Yet, the Federal Circuit's ruling *presumes* that those products infringe the patents and *presumes* that royalties are due based simply on the patentee's vague assertion of infringement. Under this standard, patent licensors could demand royalties from licensees for every product they make due to asserted infringement of every licensed patent, knowing that they will have no affirmative burden to prove their assertions.

The petition for a writ of certiorari should be granted.

STATEMENT

A. Factual Background

Petitioner Medtronic, one of the world's largest medical device companies, manufactures and sells thousands of products for use in various medical fields, including cardiac rhythm disease management, spinal and biologics, cardiovascular disease, neuromodulation, diabetes, surgical technologies, and emergency response systems. Medtronic's cardiovascular products include implantable cardiac stimulation devices, which help a patient maintain a normal heart rate or rhythm.

Respondent Mirowski Family Ventures, LLC ("MFV") is the owner of U.S. Reissue Patent Nos. RE38,119 and RE39,897. The patents together contain over 300 individual claims, and are generally directed to a "cardiac resynchronization therapy" device, which detects a cardiac signal resulting from a contraction of a first ventricle, and then sends an immediate and unconditional signal to stimulate contraction of a second ventricle. MFV has exclusively licensed the patents to Respondent Guidant, which is a wholly-owned subsidiary of Respondent Boston Scientific. App. 22a.

In 1991, following prior litigation, Medtronic entered into a license agreement with Respondents' predecessor-in-interest. App. 4a. The license agreement gave Medtronic the right to practice certain patents, including the predecessor to the two patents-in-suit, RE38,119 and RE39,897. App. 23a. The agreement provides that Medtronic will pay royalties for any products subject the license.

The agreement set out a procedure for determining whether new products developed by Medtronic were subject to royalty payments. If MFV believed that a new Medtronic product infringed a licensed patent, it was specifically required to identify the product and those patent claims it believed were infringed. Medtronic would then have the option of either paying royalties on the new devices or initiating a declaratory judgment action to challenge the alleged infringement and/or validity of the asserted MFV patents. App. 23a.

On October 3, 2007, and November 20, 2007, MFV sent letters to Medtronic accusing seven Medtronic devices of infringing 29 claims of the two patents-in-suit, and demanding royalties for those devices. Those products did not exist at the time of the 1991 license agreement, but rather were first marketed beginning in 2004. The claims MFV asserted also were only issued by the Patent Office in 2003 and 2007.

Because Medtronic did not believe that its products infringed MFV's patents, Medtronic filed this action on December 17, 2007. Medtronic's complaint sought a declaration of noninfringement and invalidity of the asserted claims.[1]

B. District Court Proceedings

Before the district court, the parties disputed who had the burden of proof regarding infringement. MFV argued that Medtronic should bear the burden because: (1) "the plaintiff usually has the burden of proof"; (2) cases placing the burden of proving infringement on the patentee were "inapposite"; and (3) the district court's guidelines provided that "the party having the burden of proof on an issue is usually permitted both an opening brief and a reply brief," and Medtronic had submitted a reply brief on the issue of infringement. App. 40a.

Due to its position, MFV did not offer any affirmative evidence of infringement. Indeed, MFV served a contention interrogatory on Medtronic, demanding that Medtronic "identify each *non-infringement* assertion." App. 44a n.10 (emphasis added).

The district court rejected MFV's argument regarding the burden of proof, noting that "'[t]he burden is always on the patentee to show infringement'" and that that burden never "'shifts to the other party—the risk of decisional uncertainty stays on the proponent of the proposition.'" App. 40a (quoting *Under Sea Indus., Inc. v. Dacor Corp.*, 833

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[1] This petition is limited to the issue of the burden of proof regarding noninfringement. Other litigated issues, such as validity and claim construction, are accordingly not summarized.

F.2d 1551, 1557 (Fed. Cir. 1987) and *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008)).

The district court held that Respondents had failed to prove that Medtronic's products infringed the patents either literally or under the doctrine of equivalents. App. 44a-52a. Respondents had submitted an expert report that, as the district court found, did not show that the expert "considered each limitation of each asserted claim in comparison to each accused product." App. 49a. The expert's report and testimony regarding infringement under the doctrine of equivalents, *see Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997), likewise "fail[ed] to execute a proper doctrine of equivalents analysis." App. 52a.

The court accordingly concluded that Respondents failed to show, by a preponderance of the evidence, that the accused products infringe the asserted claims of the reissue patents either literally or under the doctrine of equivalents. App. 49a, 52a. The court accordingly entered judgment for Medtronic as to noninfringement.

C. The Federal Circuit's Decision

A panel of the United States Court of Appeals for the Federal Circuit reversed the district court's ruling regarding the burden of proof, vacated the judgment, and remanded for further proceedings. App. 15a, 187a.

The Federal Circuit began with the "well-settled" rule that a "patentee who files a complaint or counterclaim alleging patent infringement bears the burden of proving that infringement," App. 10a, as well as the "general proposition that mere role reversal in a declaratory judgment does not shift the burden" of proof, App. 10a. In an ordinary patent declaratory-judgment action, these principles produce a scenario in which "a declaratory judgment action of invalidity with an infringement counterclaim is nothing more than an inverted infringement suit," and the patentee retains the burden of proof on infringement. App. 11a.

The Federal Circuit departed from those settled principles, however, ruling that they did not apply in the "post-*MedImmune* world." App. 9a. The Federal Circuit ruled that, in this case, "as sanctioned by *MedImmune*, the continued existence of the license precludes the very infringement counterclaim that normally would impose the burden of proving infringement on the patentee." App. 12a. Although the Federal Circuit recognized that "Medtronic's suit for declaratory judgment undoubtedly rests upon the infringement provisions laid out in [35 U.S.C.] § 271," the fact that "the relief it seeks relates directly to its obligations under the license" changed the burden of proof, because in the court's view "it is Medtronic and not MFV that is asking the court to disturb the status quo ante and to relieve it from a royalty obligation it believes it does not bear." App. 12a-13a. In that context, the Federal Circuit ruled, courts should presume that the accused products infringe unless proven otherwise. App. 13a ("If neither party introduced any evidence regarding infringement or noninfringement there is no principled reason why Medtronic should receive the declaration of noninfringement it seeks.").

The Federal Circuit summarized its holding as follows: "[W]hen an infringement counterclaim by a patentee is foreclosed by the continued existence of a license, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion." App. 14a.

The Federal Circuit denied Medtronic's petition for rehearing and rehearing *en banc*. App. 84a-85a.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's Decision Conflicts with this Court's Precedent and Settled Principles of Federal Civil Procedure.

The Federal Circuit's decision conflicts with the fundamental principle of patent litigation that a patentee must prove infringement—a principle that the court acknowledged, but erroneously concluded was inapplicable to a declaratory judgment brought under *MedImmune*.

This Court has long held that when an issue of patent infringement is contested, it is the patentee, not the accused infringer, that bears the burden of proving infringement. App. 10a; *see also R.R. Co. v. Mellon*, 104 U.S. 112, 119 (1881) ("Infringement must ... be shown by satisfactory proof; it cannot be presumed."); *Cammeyer v. Newton*, 94 U.S. 225, 231 (1877) ("Infringement is alleged by the complainants, and the burden is upon them to prove the allegation, as it imputes a wrongful act to the respondents.").

Assignment of the burden of proof is a substantive, and not merely procedural, rule of law. *See, e.g., Raleigh v. Illinois Dep't of Revenue,* 530 U.S. 15, 20-21 (2000) ("Given its importance to the outcome of cases, we have long held the burden of proof to be a 'substantive' aspect of a claim." (emphasis supplied)); *Dir., Office of Workers' Comp. Programs v. Greenwich Collieries,* 512 U.S. 267, 271 (1994) ("[T]he assignment of the burden of proof is a rule of substantive law ...."); *Dick v. New York Life Ins. Co.,* 359 U.S. 437, 446 (1959) ("[P]resumptions (and their effects) and burden of proof are 'substantive' ...."). Such substantive rights are unaffected by the declaratory nature of a proceeding, and do not vary simply because a party brings an action for declaratory judgment. *See Beacon Theatres, Inc. v. Westover,* 359 U.S. 500, 508-509 (1959) ("the plan of ... the Declaratory Judgment Act [was] to effect substantial procedural reform while ... leaving substantive rights unchanged"); *see id.* at 514 (Stewart, J., dissenting) ("[T]he Declaratory Judgment Act did not 'expand' the substantive law."); *United States v. West Virginia,* 295 U.S. 463, 475 (1935) ("[The Declaratory Judgment Act] does not purport to alter the character of the controversies which are the subject of the judicial power under the Constitution.").[2]

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[2] *See also CGM, LLC v. BellSouth Telecommunications, Inc.,* 664 F.3d 46, 55 (4th Cir. 2011) ("[The Declaratory Judgment Act] is remedial only and neither extends federal courts' jurisdiction nor creates any substantive rights.");

Consistent with these principles, this court has held (and the Federal Circuit recognized) that "mere role reversal in a declaratory judgment action does not shift the burden." App. 11a; *see also Imhaeuser v. Buerk*, 101 U.S. 647, 662 (1880) ("[T]he burden to prove infringement never shifts."); 3D Moore's Federal Practice § 57.62[2][d] ("In patent, copyright, and trademark cases, courts have generally recognized that any role reversal occasioned by declaratory relief should not shift the burden of proof from the manner in which it would be assigned in a coercive infringement suit.") (collecting cases); *cf. Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (finding it "immaterial" to a determination of whether an Article III controversy exists that "in the declaratory judgment suit, the position of the parties in the conventional suit are reversed; the inquiry is the same in either case"); *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 244 (1937) ("But the

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Medical Assur. Co. v. Hellman, 610 F.3d 371, 377 (7th Cir. 2010) ("[The Declaratory Judgment Act] does not, and arguably could not, affect the underlying substantive state and federal laws that define the rights of the parties. A federal court applying the Declaratory Judgment Act must evaluate the parties' rights based on the same body of substantive law that would apply in a conventional action."); *Hanson v. Wyatt*, 552 F.3d 1148, 1157 (10th Cir. 2008) ("The Declaratory Judgment Act does not create substantive rights." (alterations omitted)); *B. Braun Med. Inc. v. Abbott Labs.*, 124 F.3d 1419, 1428 (Fed. Cir. 1997) ("Given that the Act merely provides a new noncoercive remedy, it should come as no surprise that the practice in declaratory judgment actions is, on almost every point, the same as in any civil action." (internal quotation marks omitted)).

character of the controversy and of the issue to be determined is essentially the same whether it is presented by the insured or by the insurer.... It is the nature of the controversy, not the method of its presentation or the particular party who presents it, that is determinative.").

Despite recognizing these principles, the Federal Circuit created a gaping exception to them in what it called "the post-*MedImmune* world." App. 9a. But nothing in *MedImmune* or the nature of the declaratory judgment action it permitted envisions that a licensee will be required to shoulder the burden of proving *noninfringement*, contrary to the ordinary procedure in a patent infringement case (including most declaratory judgment cases).

This case does not meaningfully differ from a traditional declaratory judgment action for noninfringement in response to a patentee's assertion of infringement. The controversy began not with any assertion by Medtronic, but with MFV's assertion that Medtronic's products infringed its patents and demand for royalties in the amount fixed by the license agreement. MFV's assertion amounted to a contention that, unless Medtronic paid, it would be in breach of the license and subject to a patent infringement suit, in which Medtronic "could be ordered to pay treble damages and attorney's fees, and could be enjoined from selling" its products. *MedImmune*, 549 U.S. at 122. Rather than "risk such serious consequences," Medtronic paid the demanded royalties into a set aside account and began this action. *Id.*

The Federal Circuit misinterpreted this situation as one in which MFV did not "seek[] money damages ... based on patent infringement" (App. 14a), but rather sought "nothing more than to be discharged from the suit" (App. 12a). MFV of course seeks more than that; it seeks the royalties that it initially demanded for the products that *it asserted* infringed its patents. Although Medtronic was the party that initiated this action after MFV asserted infringement (as this Court envisioned in ***MedImmune***), that does not alter the fact that MFV seeks royalties from Medtronic, nor should it affect the allocation of the burden of proof.[3]

Indeed, the only difference between this case and a traditional infringement suit is that the parties have, through the license agreement, already fixed the measure of damages to be paid in the event of an adjudication of infringement.[4] There is no reason to think that that agreement about *damages*, without more, alters the burden of proof with respect to *liability*.

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[3] Medtronic does not deny its obligation to pay royalties on products actually covered by the license; indeed, it has already paid millions in royalties to MFV under the license. The breadth of the license is yet another reason Medtronic did not wish to repudiate it, as the consequences would have extended more broadly than the products at issue in this case. Instead, it sought to do just as the licensee in ***MedImmune*** did: to put the patentee's infringement contention before the district court for adjudication.

[4] There is nothing unusual about parties stipulating to the amount a patentee will recover if infringement is found. *E.g.*, Brief for Respondents 11, *Microsoft Corp. v. AT&T Corp.*, No. 05-1056 (reporting that the parties entered into an agreement that preserved Microsoft's challenge to liability for infringement and "prescribe[d] different dollar amounts that Microsoft must pay AT&T depending on the outcome").

Nor was the Federal Circuit correct that the controversy over infringement "had already been resolved by the license" (App. 14a); nothing in a *1991* license agreement resolved, or could have resolved, the question whether products Medtronic began marketing in 2004 infringed patent claims that were issued in 2003 and 2007. Rather, the license expressly provided that a disagreement over such a matter would be adjudicated in the way this Court envisioned in *MedImmune*: through a declaratory judgment action.

In such a situation, there is certainly a "principled reason" (App. 13a) for requiring the patentee to prove its entitlement to royalties. Although the licensee is nominally the declaratory judgment plaintiff, the matter in controversy is whether the patentee is entitled to take the licensee's money as compensation for infringement. There is, by contrast, no principled reason for presuming, as the Federal Circuit did, that products not identified in the license agreement and that did not exist at the time of the agreement infringe patent claims that likewise were not issued at the time of the agreement.[5]

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[5] Contrary to the Federal Circuit's suggestion, nothing in the license "foreclosed" MFV from counterclaiming for infringement. App. 14a. MFV had no *need* to do so, because Medtronic was continuing to pay royalties under protest on the disputed products into a set-aside account, but it was not precluded from doing so.

The Federal Circuit sought to rely on insurance coverage decisions, which it believed were "consistent" with its shifting of the burden of proof. App. 13a-14a. Contrary to the Federal Circuit's view, however, the lower courts are at best divided on allocating the burden of proof in the insurance context. "[S]ome courts believe that the insurer should bear the burden of proof when the insurer is the declaratory relief plaintiff," while "other courts argue that if the insured would have to prove entitlement to coverage or benefits in a coercive suit on the policy, the insured must still bear the burden of proof in a declaratory relief action initiated by the insurer." 3D *Moore's Federal Practice* § 57.62[2][d]; *see, e.g., Am. Eagle Ins. Co. v. Thompson*, 85 F.3d 327, 331 (8th Cir. 1996) (placing burden of proof on declaratory judgment defendant because he "asserted the affirmative of the question asked of the jury and ... would lose in the absence of any evidence on the issue"). The division among lower courts on this issue in the insurance context would be reason enough to grant certiorari; the Federal Circuit's importation of that disagreement into the patent context is all the more reason to do so, particularly given the consequences that the ruling below will have if left undisturbed. *See infra* Part II.

Moreover, courts that shift the burden from the insured to the insurer as a declaratory judgment plaintiff often do so based on a concern that an unsuspecting insured should not be hauled into court and then required to bear a burden of proof. *See, e.g., Am. Eagle*, 85 F.3d at 331; *Fireman's Fund*

Ins. Co. v. Videfreeze Corp., 540 F.2d 1171, 1175 (3d Cir. 1976). That concern does not arise in declaratory judgment actions under *MedImmune*, where the patentee/declaratory judgment defendant begins the controversy by demanding royalties based on an assertion of patent infringement—and particularly where, as here, the parties' agreement *expressly envisions* that the licensee may seek adjudication of that demand through a declaratory judgment action like this one. App. 23a-24a.

By shifting the burden of proof, the Federal Circuit sharply undercut the value of this Court's holding in *MedImmune*, which envisioned that a licensee could place a patentee's demand for royalty payments before a federal court without having to breach the license and invite a coercive infringement suit from the patentee. Under the Federal Circuit's rule, a licensee who wishes to pursue that route must incur a significant cost, namely a *presumption* that its products infringe and the concomitant risk of loss if the evidence is in equipoise. A licensee who wishes to force the patentee to prove the infringement contentions that the patentee first raised by demanding royalties must apparently follow the disfavored course of baiting the patentee into assuming the role of infringement plaintiff—thereby assuming for itself the risk of multiple damages and an injunction. There is no basis for requiring that state of affairs, which (as this Court recognized in *MedImmune*) is contrary to the very purpose of the declaratory judgment remedy. *See* 549 U.S. at 122. At the very least, this Court should review the case to determine whether *MedImmune* truly meant so little.

II. Unless Reversed, The Federal Circuit's Decision Will Have Far-Reaching Negative Effects.

The Federal Circuit's decision would fundamentally change the law governing relationships among licensees and licensors, to the detriment of innovation and dispute resolution, and with no evident benefit. The Federal Circuit's decision effectively creates a legal presumption of infringement in any *MedImmune*-type declaratory judgment action between a licensee and a patent licensor by placing the burden on a licensee to prove a negative—the absence of infringement.

While proving a negative is always difficult and rarely required (*see, e.g.*, *Miller* v. *California*, 413 U.S. 15, 22 (1973) (requiring prosecution "to prove a negative" imposed "a burden virtually impossible to discharge")), it is particularly difficult in a patent infringement case. Patents typically contain dozens, often hundreds of individual claims, infringement of any one of which triggers liability. *See, e.g.*, *Bio–Technology Gen. Corp.* v. *Genentech, Inc.*, 80 F.3d 1553, 1562 n.8 (Fed. Cir. 1996) ("Infringement of one valid and enforceable patent claim is all that is required for liability to arise.")

Moreover, a patent may be infringed not only literally—if every limitation of a claim is present in the accused product (*see Cross Med. Prods., Inc.* v. *Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310

(Fed. Cir. 2005))—but also under the doctrine of equivalents, if the accused product "'performs substantially the same function in substantially the same way to obtain the same result.'" *Warner-Jenkinson*, 520 U.S. at 38 (quoting *Machine Co. v. Murphy*, 97 U.S. 120, 125 (1877)). But infringement under the doctrine of equivalents may turn on many different theories of equivalence that are not evident on the face of the patent, but are only developed through expert testimony in litigation. *See, e.g.*, *AquaTex Industries, Inc.* v. *Techniche Solutions*, 479 F.3d 1320, 1329 (Fed. Cir. 2007) ("[T]he difficulties and complexities of the doctrine [of equivalents] require that evidence be presented to the jury or other fact-finder through the particularized testimony of a person of ordinary skill in the art, typically a qualified expert, who (on a limitation-by-limitation basis) describes the claim limitations and establishes that those skilled in the art would recognize the equivalents.")

Requiring a licensee to prove noninfringement would require it to anticipate and refute all theories under which the accused products could said to perform in "substantially the same way" as the claimed invention. Indeed, in this very case, Respondents tried to require Medtronic to do just that, submitting what the district called "vague perfunctory testimony" on the issue because they believed that it was Medtronic's duty to dispel a presumption of infringement.

The Federal Circuit's rule will also increase the frequency of patent litigation, because it undermines the utility of several means by which parties have heretofore avoided disputes over products not yet in existence. The Federal Circuit's rule will be particularly problematic in situations where industry participants pool their collective resources in a standards-setting organization, which this Court has recognized creates "significant procompetitive advantages." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 501 (1988). To prevent patentees from claiming ownership of widely-applicable standards (known as "patent hold-up"), standards organizations typically require members to identify all of their patents that are "essential" to the collectively-developed standard and to license the declared-essential patents on reasonable terms. *See Apple, Inc.* v. *Motorola, Inc.*, 869 F. Supp. 2d 901, 911-912 (N.D. Ill. 2012) (Posner, J., sitting by designation); Lemley & Shapiro, *Patent Holdup and Royalty Stacking*, 85 Tex. L. Rev. 1991, 2025-2029 (2007)

But most standards-setting organizations allow members to decide *unilaterally* whether one of their patents is "essential" to a standard. It is accordingly not uncommon for a licensee to dispute whether such a patent (i) is actually essential, and (ii) covers one or more of the licensee's standard-compliant products. Under *MedImmune*, licensees faced with this type of dispute should be able to file declaratory judgment actions in order to force the patentee to prove its assertion of infringement (and of essentiality).

Under the Federal Circuit's new burden-shifting scheme, however, a licensee to a standards-essential patent who launches a declaratory judgment action will be presumed to infringe, merely because the patentee unilaterally declared the patent to be "essential" and agreed to a license. This drastic change will upset settled expectations and chill the willingness of parties to enter into future licenses involving standards-essential patents.

The same holds true with respect to the broad patent cross-licenses that allow industry participants to promote innovation and protect freedom to operate by securing mutual "patent peace." See *United States v. Line Material Co.*, 333 U.S. 287, 291 (1948) ("Only when both patents could be lawfully used by a single maker could the public or the patentees obtain the full benefit of the efficiency and economy of the inventions."). A party accused of infringing a patent falling within the scope of such a cross-license could, under *MedImmune*, file a declaratory judgment action and force the patentee to prove its infringement allegations. The Federal Circuit's new regime, however, will require the cross-licensee to prove that it is not an infringer, thereby decreasing incentives for parties to resolve actual and prospective disputes via broad cross-licenses to each other's patent portfolios.

This Court has long recognized that patent licensees should not face undue obstacles in their efforts to resolve disputes regarding their obligations to licensors. *See Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). The Federal Circuit's decision in this case improperly encumbers the protection afforded by *MedImmune*, by requiring the licensee to assume the burden of proof on the issue of infringement as a price of filing a declaratory judgment action. The Federal Circuit also unnecessarily imposed a cost on licensees who attempt, in good faith, to develop products that are *not* covered by a licensed patent; such products would nonetheless be *presumed* to infringe simply upon the patentee's assertion.

The Federal Circuit's ruling also rewards licensors who make out-of-court demands for royalties based on general assertions that the licensee's products infringe any of the licensed patents, knowing that the licensor has no requirement actually to prove those infringement allegations. Nothing in *MedImmune* requires or recommends such a drastic departure from the settled principle that the patentee always bears the burden of proving its infringement allegations.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Mark C. Fleming	Martin R. Lueck
Wilmer Cutler Pickering	*Counsel of record*
Hale and Dorr LLP	Jan M. Conlin
60 State Street	Stacie E. Oberts

Boston, MA 02109
(617) 526-6000

Robins, Kaplan,
Miller &
Ciresi LLP
2800 LaSalle Plaza
800 LaSalle Ave.
Minneapolis, MN
55402
(612) 349-8500

Attorneys for
Petitioner
March 14, 2013

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APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MEDTRONIC INC.,
Plaintiff-Cross Appellant,

v.

BOSTON SCIENTIFIC CORPORATION
AND GUIDANT CORPORATION,
Defendants,

AND
MIROWSKI FAMILY VENTURES, LLC,
Defendant-Appellant.

2011-1313, -1372

Appeals from the United States District Court for the District of Delaware in No. 07-CV-0823, Judge Sue L. Robinson.

Decided: September 18, 2012

MARTIN R. LUECK, Robins, Kaplan, Miller & Ciresi L.L.P., of Minneapolis, Minnesota, argued for plaintiff-cross appellant. With him on the brief were JAN M. CONLIN and STACIE E. OBERTS.

ARTHUR I. NEUSTADT, Oblon, Spivak, McClelland, Maier & Neustadt, LLP, of Alexandria, Virginia, argued for defendant-appellant. With him on the brief were THOMAS J. FISHER and JOHN F. PRESPER.

Before LOURIE, LINN, and PROST, Circuit Judges.

LINN, Circuit Judge.

Medtronic, Inc. ("Medtronic") filed a complaint in the United States District Court for the District of Delaware seeking declaratory judgment of noninfringement and invalidity of Mirowski Family Ventures, LLC's ("MFV") U.S. Reissue Patents No. RE'38,119 ("RE'119 Patent") and No. RE 39,897 ("RE'897 Patent"). The district court entered judgment of noninfringement in favor of Medtronic and judgment of validity and enforceability in favor of MFV. *Medtronic, Inc. v. Boston Scientific Corp.*, 777 F. Supp. 2d 750 (D. Del. 2011). MFV appeals the district court's judgment of noninfringement and Medtronic cross appeals the district court's claim construction on which its judgment of validity is based.[1] Because the district court relied on a legally incorrect allocation of the burden of proof to find noninfringement in the limited circumstances of this case and incorrectly construed the claim terms in question, this court vacates and remands.

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[1] Medtronic has not appealed the district court's enforceability ruling and that issue is therefore not considered in this appeal.

I. BACKGROUND

Between 1969 and 1980, Dr. Morton Mower ("Mower") worked with Dr. Mieczyslaw Mirowski to develop the first implantable cardioverter defibrillator ("ICD"). An ICD is a device that is implanted into a patient's chest to monitor the patient's heartbeat. When the ICD detects a very rapid heartbeat that could cause cardiac arrest, it shocks the heart causing all muscle fibers to contract and resynchronize with the sinus node. Thus, the ICD is intended to prevent sudden death from heart attack, but is not designed to improve the general efficacy of the heart. The ICD is therefore not effective for treating heart conditions like congestive heart failure, where the underlying problem is the heart's decreasing ability to pump enough blood.

Between the 1960's and 1980's, Mower also analyzed EKG readings from congestive heart failure patients. Mower realized that slow conduction from one side of the heart to the other might be the cause of the incoordinate contractions that play a role in heart failure. Based on this observation, Mower developed what he called a biventricular pacer, a device that ultimately became known as a cardiac resynchronization therapy ("CRT") device. Mower's CRT device increases the heart's efficacy by causing both the patient's left and right ventricles to contract simultaneously as the heart beats. Mower ultimately patented the CRT device in what are now the RE'119 and RE'897 Patents, both assigned to MFV. MFV exclusively licenses both patents to Guidant Corp.

Medtronic is a leading manufacturer of medical devices and equipment. In 1991, Medtronic entered into a sublicense agreement covering the RE'119 Patent with Eli Lilly & Co., Guidant's predecessor-in-interest of the patents-in-suit. That agreement allowed Medtronic to challenge the RE'119 Patent's validity, enforceability, and scope via a declaratory judgment action. In 2003, as required by the sublicense, Medtronic began paying royalties into escrow while challenging the validity of the RE'119 Patent. Ultimately the parties entered into a Litigation Tolling Agreement ("LTA") that tolled litigation and obligated MFV to inform Medtronic of which Medtronic products MFV deemed were covered by the RE'119 Patent, or subsequent reissue patents claiming priority from the RE'119 Patent (here, the RE'897 Patent), and subject to royalty payments. If Medtronic disagreed, the LTA gave Medtronic the right to retain its license and obligated Medtronic to seek a declaratory judgment of noninfringement in the United States District Court for the District of Delaware. In October and November of 2007, MFV identified several Medtronic products that MFV thought practiced its patents. Pursuant to the LTA, on December 17, 2007, Medtronic filed the complaint giving rise to this declaratory judgment action. Because Medtronic remained MFV's licensee, MFV could not counterclaim for infringement of either patent.

Throughout this litigation the parties have disagreed over whether MFV, the patentee, bore the burden of proving infringement, or whether Medtronic, the declaratory judgment plaintiff, bore the burden of proving noninfringement. During discovery, MFV propounded an interrogatory requesting Medtronic to state the basis for its allegation in paragraph twenty-four of its complaint that "Medtronic's Accused Devices do not infringe any valid claim of the '119 Reissue Patent or the '897 Reissue Patent." Complaint at 6, *Medtronic, Inc. v. Boston Scientific Corp.*, No. 07-CV-0823 (D. Del. Mar. 30, 2011), ECF No. 1. Medtronic objected to MFV's interrogatory, maintaining that the burden to prove infringement rested on MFV and that MFV had failed to provide its infringement contentions. Medtronic ultimately responded to the interrogatory with reasons why it felt that its products do not infringe MFV's patents. On the date expert reports were due, Medtronic served the report of its expert, Dr. Charles Love ("Love"). MFV subsequently served the report of its expert, Dr. Ronald Berger ("Berger"). Consistent with MFV's contention that Medtronic bore the burden to prove noninfringement as it alleged in its complaint, Berger's report was largely responsive to Love's report, and Berger admitted that he did not expressly map the products in question to every limitation of the relevant claims. *Medtronic, Inc. v. Boston Scientific Corp.*, No. 07-CV-0823, slip op. at 22-23 (D. Del. Mar. 30, 2011) ("*Opinion*").

The district court held a bench trial on January 25-28, 2010, and March 13, 2010. The court relied on *Under Sea Industries, Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987), which states that "[t]he burden always is on the patentee to show infringement," and thus held that "[a]s the parties asserting infringement, defendants bear the burden of proof by a preponderance of the evidence." *Opinion* at 17. "Having determined that defendants, as patentees, have the burden to prove infringement," *id.* at 20, the court found that Berger's testimony lacked sufficient foundation because of his failure to consider "each limitation of each asserted claim in comparison to each accused product before rendering his infringement opinions," and that defendants "failed to prove literal infringement by a preponderance of the evidence," *id.* at 24. The court also found Berger's report and testimony conclusory and insufficient to show that the products infringe the patents under the doctrine of equivalents. *Id.* at 25-26.

Finally, the district court, in conducting its claim construction, relied on portions of the specification that describe the invention in the context of treating congestive heart failure to construe the preamble terms "improving the hemodynamic efficiency of a heart," RE'119 Patent col. 10 ll. 1-2, 25-26, and "bi-ventricular pacemaker," RE'119 Patent col. 11 l. 1, col. 12 l. 1, as limited to the treatment of congestive heart failure. *Opinion* at 12-14; *see, e.g.*, RE'119 Patent col. 1 ll. 18-22 (stating in the specification that "[t]his invention pertains to . . . a method for increasing the cardiac output of a patient suffering from congestive heart failure by stimulating the heart of the patient at multiple sites simultaneously"), col. 3 ll. 13-15 (stating in the specification that "an objective of the present invention is to provide a cardiac pacer for increasing hemodynamic efficiency of a heart experiencing a conduction deficiency.").

MFV appeals the district court's grant of declaratory judgment of no literal infringement and no infringement under the doctrine of equivalents. Medtronic cross appeals the district court's claim construction ruling. This court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

Claim construction is a question of law that this court reviews de novo. *Cybor Corp. v. FAS Techs.*, 138 F.3d 1448, 1451 (Fed. Cir. 1998) (en banc). This court also reviews a district court's other legal conclusions, such as who bears the burden of proof, de novo. *Madey v. Duke Univ.*, 307 F.3d 1351, 1358 (Fed. Cir. 2002).

B. Burden of Proof

MFV argues that because Medtronic is the declaratory judgment plaintiff--the party seeking court action--Medtronic bore the burden of proving noninfringement, a burden it failed to carry. MFV further explains that because of the parties' licensing agreement, it could not have filed a counterclaim for infringement and the court erred by viewing MFV as a party "asserting infringement." *Opinion* at 17. MFV points out that all of the cases the district court relied on to conclude that MFV bore the burden to prove infringement are conventional claims for patent infringement by the patentee as contrasted with declaratory judgment actions by licensees. MFV also points out that the parties' agreement requires Medtronic to initiate litigation by filing a declaratory judgment action, as it has done in this case, making

Medtronic the party seeking relief from the court. Thus, according to MFV, because Medtronic filed a complaint seeking a judgment that its products do not infringe MFV's patents, Medtronic should have to prove that at least one limitation of each claim of MFV's patents is not met by Medtronic's products.

Medtronic counters that, as the district court held, the burden of proving patent infringement always lies with the patentee; that burden never shifts to the accused infringer. *Opinion* at 17. Medtronic cites *Under Sea Industries,* 833 F.2d at 1557 ("The burden always is on the patentee to show infringement."), *Technology Licensing Corp. v. Videotek, Inc.,* 545 F.3d 1316, 1327 (Fed. Cir. 2008) (burden never shifts to an accused infringer), and *Laitram Corp. v. Rexnord, Inc.,* 939 F.2d 1533, 1535 (Fed. Cir. 1991) (patentee must demonstrate every element of the claim), as support for its position. Medtronic also finds the District of Maryland's reasoning persuasive in *MedImmune, Inc. v. Centocor, Inc.,* 271 F. Supp. 2d 762 (D. Md. 2003), where, on similar facts, the court placed the burden on the patentee. Finally, Medtronic argues that because MFV complied with the requirement of the LTA to first notify Medtronic of the products accused to infringe before Medtronic filed the declaratory judgment action, MFV was in fact the party to "assert infringement" notwithstanding that it did not and could not file an infringement counterclaim.

The question before us arises as a consequence of the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.,* 549 U.S. 118 (2007). In *MedImmune* the Court found declaratory judgment jurisdiction notwithstanding the fact that the declaratory judgment plaintiff licensee continued to make royalty payments pursuant to a license. The Court reasoned that a licensee should not be forced to cease royalty payments and risk infringement liability before the licensee can challenge the extent of coverage of the license. *MedImmune,* 549 U.S. at 134. Thus, *MedImmune* provided licensees with a shield from the economic consequences of challenging their licensors' patents while enabling those licensees to file declaratory judgment suits to clarify the rights and obligations of the parties under their license agreements. This case requires us to determine the proper allocation of the burden of persuasion in the post-*MedImmune* world, under circumstances in which a declaratory judgment plaintiff licensee seeks a judicial decree absolving it of its responsibilities under its license while at the same time the declaratory judgment defendant is foreclosed from counterclaiming for infringement by the continued existence of that license.

Generally, the party seeking relief bears the burden of proving the allegations in his complaint. *See Schaffer ex rel. Schaffer v. Weast,* 546 U.S. 49, 56-57 (2005). "Perhaps the broadest and most accepted idea is that the person who seeks court action should justify the request . . . ." *Schaffer,* 546 U.S. at 56 (quoting C. Mueller & L. Kirkpatrick, *Evidence* § 3.1, p. 104 (3d ed. 2003)). "The burdens of pleading and proof with regard to most facts have been and should be assigned to the plaintiff who generally seeks to change the present state of affairs and who therefore naturally should be expected to bear the risk of failure of proof or persuasion." *Id.* (quoting 2 J. Strong, *McCormick on Evidence* § 337, p. 412 (5th ed. 1999)). In *Schaffer*, a school district denied a student educational services under the Individuals with Disabilities Education Act. *Id.* at 54-55. The student filed suit against the school district and the Court considered which party bore the burden of proving the student was entitled to the services. After finding no guidance in the statute the Court applied "the ordinary default rule that plaintiffs bear the risk of failing to prove their claims," *id.* at 56-57, and placed the burden on the student, "where it usually falls, upon the party seeking relief," *id.* at 58.

It is, of course, well settled that a patentee who files a complaint or counterclaim alleging patent infringement bears the burden of proving that infringement. *See Under Sea Indus.*, 833 F.2d at 1557; *In re Tech. Licensing Corp.*, 423 F.3d 1286, 1288-89 (Fed. Cir. 2005); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2007); *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991). In the absence of a license, this court has recognized "that when the same patent is at issue in an action for declaration of non-infringement, a counterclaim for patent infringement is compulsory and if not made is deemed waived." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 802 (Fed. Cir. 1999).

The substantive burden of proof normally does not shift simply because the party seeking relief is a counterclaiming defendant in a declaratory judgment action. *See In re Tech. Licensing Corp.*, 423 F.3d at 1288-89 (citing *In re Lockwood*, 50 F.3d 966, 976

(Fed. Cir. 1995) and recognizing that a declaratory judgment action of invalidity with an infringement counterclaim is nothing more than an inverted infringement suit); *Ranbaxy Pharms. Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1237, 1239-40 (Fed. Cir. 2003) (requiring patentee seeking preliminary injunction on infringement counterclaim to show *inter alia* a likelihood of proving infringement). In *Vivid Technologies*, this court explained that "the parties bore the same evidentiary burdens whether or not the counterclaim was permitted," but did not further discuss what those burdens were. 200 F.3d at 802. Moreover, that statement was made before the Supreme Court's *MedImmune* decision and was based on the general proposition that mere role reversal in a declaratory judgment action does not shift the burden. *Id.* Specifically, *Vivid Technologies* quoted *Moore's Federal Practice* that "in patent cases 'courts have generally recognized that any role reversal occasioned by declaratory relief should not shift the burden of proof from the manner in which it would be assigned in a coercive infringement suit.'" *Id.* (quoting 12 James Wm. Moore et al., *Moore's Federal Practice* 57.62[2][d] (3d ed. 1997)). But *Moore's Federal Practice* did not consider allocating the burden of proof post-*MedImmune*, when "a coercive infringement suit" was not possible and therefore did not address Medtronic's simple role reversal argument at issue here.

These cases only stand for the rote proposition that when there is a direct claim for infringement, in a complaint or by way of counterclaim, the patentee cannot prevail without proving all the elements of infringement under 35 U.S.C. § 271. And in the customary declaratory judgment case, like *Vivid Technologies*, the declaratory judgment defendant must assert a counterclaim for infringement to avoid risking the loss of that claim forever. *See id.* But this is not such a case. In this case, as sanctioned by *MedImmune*, the continued existence of the license precludes the very infringement counterclaim that normally would impose the burden of proving infringement on the patentee. Here, Medtronic is shielded from any liability for infringement by its license. And MFV has not asserted a claim of infringement, nor could it because of the license. Thus, while Medtronic's suit for declaratory judgment undoubtedly rests upon the infringement provisions laid out in § 271, the relief it seeks relates directly to its obligations under the license.

The contract at issue here required MFV to identify products it believed were covered by the contract. After MFV identified those products, Medtronic was required to either pay royalties on them, or sue for declaratory judgment that the products were not covered. Medtronic is unquestionably the party now requesting relief from the court: it already has a license; it cannot be sued for infringement; it is paying money into escrow; and it wants to stop. In contrast, regarding the patents at issue here, MFV seeks nothing more than to be discharged from the suit and be permitted to continue the quiet enjoyment of its contract.[2] In other words, it is Medtronic and not

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[2] MFV initially counterclaimed for declaratory judgment of its right to recover money paid into escrow under the 2003 escrow agreement regarding U.S. Patent No. 4,407,288. This counter-

MFV that is asking the court to disturb the status quo ante and to relieve it from a royalty obligation it believes it does not bear. Consistent with the above, for the court to disturb the status quo ante, Medtronic must present evidence showing that it is entitled to such relief. If neither party introduced any evidence regarding infringement or noninfringement there is no principled reason why Medtronic should receive the declaration of noninfringement it seeks.

This analysis is fully consistent with other areas of the law. In insurance cases, courts generally place the burden on the party seeking recovery under a policy. This is true even when the insured is the declaratory judgment defendant. *See Am. Eagle Ins. Co. v. Thompson,* 85 F.3d 327, 331 (8th Cir. 1996) ("Stripped of its procedural posture, this action is, at base, a claim by Thompson [the insured who ultimately bore the burden] that he is covered under an insurance policy and a denial by the insurer [declaratory judgment plaintiff] that coverage properly exists."). But the burden can shift to the declaratory judgment plaintiff where the insured is not seeking affirmative relief. *See Reliance Life Ins. Co. v. Burgess,* 112 F.2d 234, 237 (8th Cir. 1940) (holding that when the declaratory judgment defendant insureds "asked no affirmative relief [and] prayed only to be discharged with their costs," the burden fell on the declaratory judgment plaintiff insurance company). The Third Circuit cited Burgess as "[t]he leading case which expounded the[] guiding principles" for

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claim was dismissed without prejudice pursuant to joint stipulation by the parties and is not at issue in this appeal.

allocating the burden of proof in a declaratory judgment action. *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1175 (3d Cir. 1974) (also noting that the burden often falls on the insurer in personal disability insurance cases where the issue is whether the insured is able to return to work and the insurer may cease making payments).

As noted, neither party here seeks money damages or an injunction based on patent infringement, which are the sorts of relief generally sought when a party seeks relief for patent infringement. Instead, the one claim for relief sought in this case is the claim Medtronic asserts to be relieved from liability under the license by having a court declare the products in question to be noninfringing. Medtronic is the party seeking this relief and Medtronic must bear the burden of proving it is entitled to such relief. A contrary result would allow licensees to use *MedImmune's* shield as a sword--haling licensors into court and forcing them to assert and prove what had already been resolved by license. Because the declaratory judgment plaintiff is the only party seeking the aid of the court in the circumstances presented here, that party must bear the burden of persuasion. Therefore, this court holds that in the limited circumstance when an infringement counterclaim by a patentee is foreclosed by the continued existence of a license, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion.

In view of the above holding, the district court's finding that Berger's expert testimony lacked sufficient foundation because his report "fail[ed] to demonstrate that [he] considered each limitation of each asserted claim in comparison to each accused product before rendering his infringement opinions" was clearly erroneous. *Opinion* at 24. MFV did not bear that burden of proof and its expert was therefore not obliged to do more than rebut Medtronic's contentions. The district court's conclusion that "[d]efendants have failed to prove literal infringement by a preponderance of the evidence" can not stand. *Id.* Because we reverse on this basis we need not reach the district court's conclusion regarding Berger's opinions on infringement by equivalents. We also need not address MFV's argument that Medtronic's interrogatory responses effectively conceded that all unaddressed claim limitations were satisfied. Because Medtronic, and ultimately the district court, did not appreciate the appropriate allocation of the burden of proof and how the burden affected the parties' conduct during discovery, it is within the district court's discretion on remand whether to limit Medtronic to its current interrogatory answer, or to allow Medtronic to amend its interrogatory answer to include any additional noninfringement contentions it may wish to assert.

C. Claim Construction

In its cross-appeal, Medtronic contends that the district court based its refusal to find the patents invalid on an erroneous claim construction. Medtronic argues that the district court improperly restricted the asserted claims of the RE'119 patent to treating congestive heart failure based only on the specification's disclosure of such treatment; nothing in the specification disclaims using the invention to treat other conditions. According to Medtronic, the specification is very broad and provides examples of treating many conditions caused by conduction deficiency--some unrelated to heart failure (e.g., bundle branch blocks). Medtronic argues that the patentee did not expressly narrow or clearly disavow a broader claim scope. Finally, Medtronic notes that claim 171 of the RE'897 Patent specifically recites the limitation of "improv[ing] the pumping ability of the heart suffering from heart failure," while the other, broader claims do not. RE'897 Patent col. 21 ll. 34-35.

MFV argues that the patentee expressly defined his invention for use only in congestive heart failure. MFV also stresses that the inventor described the invention's use for treating congestive heart failure as a way to distinguish this invention from a prior art reference ("Funke"). *See* RE'119 Patent col. 2 ll. 28-33. Finally, MFV cites *SafeTCare Manufacturing, Inc. v Tele-Made, Inc.,* 497 F.3d 1262 (Fed. Cir. 2007), to argue that it is only trying to understand what the patentee has claimed and disclaimed, not to import limitations from the specification into the claims.

"[T]he words of a claim 'are generally given their ordinary and customary meaning' . . . that the term would have to a person of ordinary skill in the art in question at the time of the invention . . . ." *Phillips v. AWH Corp.,* 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (citations omitted). That person of ordinary skill in the art is deemed to understand the terms in the context of the entire patent, including the specification, *id.* at 1313, but the claim terms should not be limited to the disclosed embodiments, *id.* at 1323. Rather, claim terms should generally be given their ordinary and customary meaning unless "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Computer Entm't Am. LLC,* 669 F.3d 1362, 1365 (Fed. Cir. 2012). "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term . . . .'" *Id.* (quoting *CCS Fitness, Inc. v. Brunswick Corp.,* 288 F.3d 1359, 1366 (Fed. Cir. 2002)). And "[w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside . . . the patent," even if the terms might otherwise be broad enough to cover that feature. *Id.* at 1366 (internal citation omitted).

Here, the district court did nothing more than append the limitation "for the treatment of congestive heart failure," onto the ends of the disputed claim terms. *Opinion* at 12-14. This unquestionably added a limitation. This would only have been proper if the patentee specifically defined the terms to include that limitation, or disavowed their otherwise broad scope. While the specification explains the use of the invention to treat congestive heart failure, it also discloses the invention's value in treating other diseases. *See, e.g.*, RE'119 Patent col. 3 ll. 13-15 ("an objective of the present invention is to . . . [treat] a heart experiencing a conduction deficiency."). As for the prior art Funke reference, the prosecution history reveals that the patentee distinguished Funke based on the placement of electrodes to stimulate only the ventricles, not based on any express use of the disclosed device to treat any particular condition. The statement in the specification that Funke does not disclose his invention's "specific use as a method of improving the cardiac output of patients suffering from congestive heart failure," RE'119 Patent col. 2 ll. 30-32, is a far cry from the clear disavowal needed to limit the claims of the RE'119 Patent. Moreover, inclusion of the express limitation "to improve the pumping ability of the heart suffering from heart failure," RE'897 Patent col. 21 ll. 33-35, in claim 171 of the RE'897 Patent, a continuation of the RE'119 Patent, suggests that the other claims that do not recite such a limitation should not be so limited. We therefore conclude that the district court erred by restricting the claimed invention to the treatment of congestive heart failure. The district court's determination of no invalidity predicated on its improper claim construction is vacated. On remand, Medtronic may press its invalidity contention based upon the correct claim construction.

CONCLUSION

For the foregoing reasons, the judgment of the district court is vacated, and the case is remanded for additional proceedings consistent with this opinion.

VACATED AND REMANDED

COSTS

Each of the parties shall bear its own costs.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

MEDTRONIC, INC.)
)
Plaintiff,)
)
v.)
)
BOSTON SCIENTIFIC) Civ. No. 07-823-
CORPORATION, GUIDANT) SLR
CORPORATION, and)
MIROWSKI FAMILY)
VENTURES L.L.C.)
)
Defendants.)

Arthur G. Connolly III, Esquire of Connolly Bove Lodge & Hutz LLP, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Martin R. Lueck, Esquire, Jan M. Conlin, Esquire and Stacie E. Oberts, Esquire of Robins, Kaplan, Miller & Ciresi L.L.P., Minneapolis, Minnesota.

Richard L. Horowitz, Esquire, David Ellis Moore, Esquire of Potter Anderson & Corroon, LLP, Wilmington, Delaware. Counsel for Defendant Mirowski Family Ventures, L.L.C. Of Counsel: Arthur J. Neustadt, Esquire, Thomas J. Fisher, Esquire and John F. Presper, Esquire of Oblon, Spivak, McClelland, Maier & Neustadt, L.L.P., Alexandria, Virginia.

Frederick L. Cottrell, III, Esquire and Anne Shea Gaza, Esquire of Richards, Layton & Finger, Wilmington, Delaware. Counsel for Defendants Boston Scientific Corporation and Guidant Corporation. Of Counsel: J. Michael Jakes, Esquire and Naveen Modi, Esquire of Finnegan Henderson Farabow Garrett & Dunner LLP, Washington, District of Columbia.

OPINION

Dated: March 30, 2011
Wilmington, Delaware

I. INTRODUCTION

Plaintiff Medtronic, Inc. ("Medtronic" or "plaintiff") filed this complaint on December 17, 2007, against Boston Scientific Corporation ("BSC"), Guidant Corporation ("Guidant"), and Mirowski Family Ventures LLC ("MFV," collectively "defendants") for declaratory judgment of non-infringement and invalidity of United States Reissued Patent Nos. RE 38,119 ("the '119 patent") and RE 39,897 ("the '897 patent," collectively "the reissue patents"). (D.I. 1) Thereafter, plaintiff amended its complaint twice, first to add a defense of prosecution laches, and then to assert non-infringement of two new products. (D.I. 84; D.I. 108) BSC and Guidant filed an answer on February 2, 2008, and thereafter amended it twice. (D.I. 18; D.I. 88; D.I. 115) MFV also filed an answer on February 2, 2008 and amended it twice. (D.I. 20; D.I. 89; D.I. 114) On December 2, 2009, the parties submitted their joint claim construction chart. (D.I. 144) The court conducted a *Markman* hearing on January 7, 2010.

A bench trial was held January 25-28 and March 13, 2010 on validity and enforceability of the reissue patents and whether any of the accused products infringe any valid asserted claim. On March 30, 2010, the parties stipulated that in post-trial briefing, plaintiff would file opening and reply briefs, and defendants would file only an answering brief. (D.I. 187) On February 7, 2011, the court ordered that defendants may file a sur-reply brief addressing only the issue of infringement as discussed in plaintiff's reply post-trial brief. (D.I. 253) Pursuant to the court's order, defendants filed a sur-reply brief on February 22, 2011. (D.I. 254) The issues at bar have been fully briefed post-trial. The court has jurisdiction pursuant to 35 U.S.C. §§ 1 et seq. and 28 U.S.C. §§ 1331, 1338(a), 1400(b) and 2201. Having considered the documentary evidence and testimony, the court makes the following findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52(a).

II. FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Background

1. The parties and litigation history

1. Medtronic, BSC, and Guidant are all leading manufacturers and sellers of medical devices. (D.I. 86 at 2) Medtronic is a Minnesota corporation with a principal place of business in Minneapolis, Minnesota. (D.I. 115 at 1) Medtronic is engaged in the business of manufacturing, promoting, offering for sale, and selling certain implantable cardiac stimulation devices that are capable of providing cardiac resynchronization therapy ("CRT"). (D.I. 114 at 1; D.I. 115 at 1) BSC is a Delaware corporation with a principal place of business in Natick, Massachusetts. (D.I. 115 at 1) Guidant is an Indiana corporation with a principal place of business in Carmel, Indiana, and is a wholly-owned subsidiary of BSC. *(Id.)* Guidant is the exclusive licensee of the reissue patents. *(Id.)* MFV is a Maryland limited

liability company which holds the patent rights of Michel Mirowski, M.D., inventor of the implantable cardiac defibrillator ("ICD"), and is the assignee of the reissue patents. (D.I. 86 at 2; D.I. 114 at 1)

2. There is a long history of litigation involving the parties in the case at bar. (See D.I. 86 at 1-8) Ely Lilly & Co. ("Lilly"), Guidant's predecessor-in-interest to the reissue patents, entered into a sublicense agreement ("Lilly agreement") with Medtronic in 1991 covering, inter alia, the '119 patent. (DTX-87 at 1) The Lilly agreement gave Medtronic the right to challenge allegations of infringement of the '119 patent as well as the validity and enforceability of the '119 patent through one or more declaratory judgment actions. (*Id.*)

3. In 2003, by agreement of the parties, Medtronic began paying royalties into escrow on sales of certain products, while at the same time challenging the validity of the '119 patent ("2003 litigation").[1] (*Id.*) In 2004, the validity and enforceability of the '119 patent was also placed at issue in litigation between Guidant and St. Jude Medical, Inc. ("St. Jude litigation").[2] (*Id.*)

4. In 2006, Medtronic, Guidant, and MFV entered into a "Litigation Tolling Agreement"

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[1] *Medtronic, Inc. v. Guidant Corp.*, No. 03-848-SLR (D. Del.)

[2] *St. Jude Medical, Inc. v. Guidant Corp.*, No. 04-0067-SLR (D. Del.)

("LTA"). (DTX-87) The LTA recognized that "an actual controversy exists . . as to the scope, validity and enforceability of the '119 patent, and whether or not any valid and enforceable claims thereof cover Medtronic products, and consequently the proper distribution of substantial monies residing in or to be paid into various escrow accounts." (*Id.* at 2) The LTA tolled and suspended various litigation and defenses thereto pending the conclusion of the "DJ Suspension Period" and for ninety (90) days after receipt by Medtronic of a notice of infringement from Guidant or MFV. (*Id.* at 5) The "DJ Suspension Period" was defined to be "the later of: (a) final resolution of the St. Jude Litigation (including settlement thereof), or (b) October 1, 2007." (*Id.* at 2) The LTA provided that, within 60 days after the DJ Suspension Period, defendants could provide written notice to Medtronic of infringement of the '119 patent or subsequent reissue patents claiming priority to the '119 patent. (*Id.* at 5) The LTA further provided that, within 90 days after such notice, Medtronic could initiate a final declaratory judgment, in this court, challenging infringement, unenforceability and/or validity of the asserted claims of the '119 patent and any asserted claims of any subsequent reissue patent(s). (*Id.* at 6) The declaratory judgment complaint in the present action was filed pursuant to the LTA. (D.I. 1)

2. The heart, its maladies and treatment

5. The human heart is divided into four chambers. (D.I. 154, ex. 1 at ¶ 22; 0.1.146 at 3) The two upper chambers of the heart are called the left

and right atria and receive blood from the body or lungs. (D.I. 154, ex. 1 at ¶¶ 22, 23; D.I. 146 at 3) "One upper chamber is called an 'atrium,' while both upper chambers together are called the 'atria.'" (D.I. 154, ex. 1 at ¶ 22) The two lower chambers in the heart are called the left and right ventricles and are the pumping chambers of the heart. (*Id.*; D.I. 146 at 3) When the ventricles contract, blood is pumped out of the heart with enough force to push blood through the lungs and entire body. (*Id.*)

6. The left and right sides of the heart are separated by a wall, called the septum. (D.I. 154, ex. 1 at ¶ 23; D.I. 146 at 3) Deoxygenated blood (blood with no oxygen) returning to the heart from the body moves through the right side of the heart. (*Id.*) Oxygenated blood (blood with oxygen) returning from the lungs moves through the left side of the heart. (*Id.*)

7. The right atrium receives deoxygenated blood from the body. (D.I. 154, ex. 1 at ¶ 22; D.I. 146 at 3) When the right atrium contracts, blood is pushed into the right ventricle. (*Id.*) Once the right ventricle has filled, it contracts and pumps blood to both lungs. (*Id.*) Blood is circulated through the lungs where carbon dioxide is removed and oxygen is absorbed. (D.I. 146 at 3)

8. Oxygenated blood returns to the heart into the left atrium. (*Id.*) When the left atrium contracts, blood is pushed into the left ventricle. (*Id.*) When the left ventricle contracts, blood is pushed on

to the rest of the body. (*Id.*) The circulatory cycle then begins again. (*Id.*)

9. A variety of problems can cause the heart to behave abnormally. (D.I. 148, ex. 1 at 5-6) One problem involves the heart's electrical system, which can affect the timing of the heart, resulting in arrhythmias (rhythm disorders). (*Id.*) One such disorder is bradycardia, a condition in which the heart beats too slowly. (*Id.*) Tachycardia, on the other hand, is a condition in which the heart beats too rapidly. (*Id.* at 7) Fibrillation is a condition in which the heartbeat is chaotic, or irregular, and the heart may skip beats. (*Id.*)

10. Treatment of these electrical disorders usually involves an implantable electronic device for stimulating the heart. (*Id.*) Bradycardia is treated using a pacemaker, a device that sends electrical impulses to the heart through electrical leads (wires) in the right atrium and right ventricle to maintain a suitable heart rate. (*Id.* at 6-7) Tachycardia and fibrillation are usually treated using an implantable cardioverter defibrillator ("ICD"). (*Id.* at 7) Compared to pacemakers, ICDs deliver a massive high- energy pulse (shock) to the heart through electrical leads to stop the arrhythmias. (*Id.*)

11. Separate from the timing problem of arrhythmias, a heart may also suffer from structural problems that affect its pumping ability, such as heart failure. (*Id.* at 8) Heart failure is a disease in which the heart progressively loses its ability to effectively pump blood. (*Id.*)

12. Pacing of the heart, using a pacemaker, is performed in various modes described by a shorthand positional notation according to at least the following three parameters: (1) the chamber(s) where pacing occurs; (2) the chamber(s) where sensing occurs; and (3) the response to sensing. (D.I. 188 at 80:23-86:10) In this notation, the chambers paced and sensed are designated by characters, where "O" represents zero or none, "A" represents atrium, "V" represents ventricle, and "D" represents dual (A+V). (*Id.*) The response to sensing is designated by the characters "O" representing zero or none, "T" representing triggered output in response to a sensed event, "I" representing inhibited output in response to a sensed event, and "D" representing dual (T+I). (*Id.*)

13. The modes relevant to the reissue patents are: VOO, VVI, VDI, VVT, VAT, and VDD. VOO mode, also known as "Fixed-rate Ventricular pacing," describes ventricular pacing with no sensing. (D.I. 188 at 82:6-21; D.I. 193 at 42) VVI mode indicates activity is sensed in the ventricle, and stimulation of one ventricle is inhibited if intrinsic electrical activity is sensed. (D.I. 188 at 83:2-24; D.I. 193 at 42) VDI mode indicates activity is sensed in the ventricle and/or atrial chambers, and stimulation of one ventricle is inhibited if intrinsic electrical activity is sensed. (D.I. 188 at 83:2-24; D.I. 193 at 42) VVT mode, or "Triggered pacing," indicates stimulation of one ventricle is triggered upon the sensing of an electrical signal in another ventricle. (D.I. 188 at 83:25-84:3; D.I. 193 at 42) VAT

mode, or "atrial-triggered, ventricular pacing," indicates that the ventricle is paced if electrical activity is sensed in an upper (atrial) chamber of the heart. (D.I. 188 at 84:19-85:4; D.I. 193 at 42) Finally, in VDD mode, stimulation of the ventricle can be inhibited or triggered if intrinsic activity in the atrial or ventricular chambers is sensed. (D.I. 188 at 85:23-86:9; D.I. 193 at 42)

3. Dr. Mower's invention

14. Dr. Mower is a renowned researcher in the cardiology field, having been inducted into the National Inventors Hall of Fame for his invention, in the 1970s with Dr. Mirowski, of the first ICD. (D.I. 189 at 479:7-481:10) As a practicing cardiologist in the 1980s, Dr. Mower concerned himself with the treatment of congestive heart failure, a condition more widespread than ventricular fibrillation for which the ICD was invented. (*Id.* at 481:20-482:8) At the time, Dr. Mower was practicing at Sinai Hospital in Baltimore, Maryland, where he "ran the heart station, which . . . did most of the EKG reading." (*Id.*) Dr. Mower noticed that "those patients who were diagnosed [with] congestive heart failure generally had widened QRSs," from which he inferred that "there was a slow conduction from one side of the heart to the other, and [] realized that there might be incoordinate contraction playing at least some role in the heart failure." (*Id.* at 488:7-22) This insight led to the invention that is the subject of the reissue patents. (*Id.* at 488:12-489:2)

15. Dr. Mower's invention is directed to a device to treat ventricular asynchrony. *Medtronic v. Guidant Corp.*, Civ. No. 03-848-SLR, 2004 WL 5501181 at *3-4 (D. Del. July 19, 2005). Ventricular asynchrony is a condition in which the patient has a conduction defect in his ventricles causing the ventricles to contract at different times. *Id.* Dr. Mower's invention addresses this defect by pacing the heart so as to cause substantially simultaneous ventricular contractions. *Id.* Unlike treating an arrhythmia (where the concern is the quantity of heartbeats), because the patient is suffering from heart failure, continuous bi-ventricular pacing improves the output of the heart and, therefore, the quality of the heartbeats. (D.I. 190 at 528:13-25) "Bi-ventricular pacing (or pacer/pacemaker)," a term used in the reissue patents, is now referred to as cardiac resynchronization therapy. ('119 patent at col. 3:56-57, col. 6:3-14, col. 7:17-20, and claims 9-13, 22-26; '897 patent, claims 132-133; D.I. 146, ex. 2 at 17)

4. The reissue patents

16. The reissue patents are both reissues of U.S. Patent No. 4,928,688 ("the '688 patent"). (Reissue patents at [64]) The '688, '119 and '897 patents are directed to a method and apparatus for treating hemodynamic dysfunction by using electrodes to simultaneously stimulate the ventricles of the heart. ('688, '119 and '897 patents, Abstract) The reissue patents share the specification and priority date of the '688 patent. (D.I. 147 at 2 n.2) The '688 patent issued on May 29,1990 from

application No. 07/299,895 ("the '895 application"), filed on January 23, 1989. ('688 patent at [21, 22, 45])

17. The '119 patent issued on May 20, 2003 from application No. 08/547,691 ("the '691 application"), filed on October 19, 1995. ('119 patent at [21, 22, 45]) The '691 application was a continuation of application No. 10/214,474, ("the '474 application") filed Aug. 8, 2002, which in turn was a continuation of application No. 07/890,280, ("the '280 application") filed May 29, 1992, which was later abandoned. ('119 patent at [63])

18. The '897 patent issued on October 23, 2007 from application No. 10/214,474, filed on August 8, 2002. ('897 patent at [21, 22, 45]) The '897 patent is a continuation of the '119 patent. ('897 patent at [63])

19. The named inventor of the reissue patents is Morton M. Mower. (Reissue patents at [75]) Since a reissued patent is valid only for the "unexpired term of the original patent," the reissue patents each expired on January 23, 2009. See 35 U.S.C. 251.

20. Defendants allege that plaintiff infringed one or more of claims 15, 19, 20, 25 and 26 of the '119 patent and claims 15, 54, 84, 86, 120, 144, 172,201, 217, 233, 248, 273, 288, 303, 308, 311, 315

and 324-328 of the '897 patent. (D.I. 188 at 4:22-25, 137:22-138:13; PTX-515[3])

5. Accused devices

21. Defendants accuse plaintiff's InSync, InSync ICD, InSync II Marquis, InSync Maximo, InSync II Protect, InSync Sentry, Concerto, Maximo II and Consulta devices (collectively "accused devices") of infringing the reissue patents. (D.I. 192 at 868:8-17; PTX-567) The accused devices are all cardiac resynchronization therapy devices. (D.I. 189 at 334:11-335:4) Although similar, slight differences exist among the accused products. (*Id.*) The InSync device does not provide defibrillation therapy, whereas the remaining accused devices are all CRT devices coupled with defibrillators. (*Id.*) Additionally, the InSync pacemaker does not have separate sensing and pacing circuitry for the two ventricular leads; instead, the leads are coupled together. (*Id.*) Some modes available in the other devices are not found in the InSync ICD. (*Id.*)

B. Claim Construction

22. The parties dispute construction of ten different terms of the asserted claims of the '119 patent. For the reasons discussed below, the court finds that only two terms, involving claim preambles, are dispositive of the issues at bar.

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[3] Claims 184 and 309 of the '897 patent were originally asserted and are shown in PTX-515, but were later withdrawn. (D.I. 188 at 4:22-24)

1. Legal standard

23. Claim construction is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The words of a claim "are generally given their ordinary and customary meaning," as understood by a person of ordinary skill in the art in question, read in the context of the particular claim and that of the entire patent, at the time of the invention. *Phillips v. AVVH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citations omitted). The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (*quoting Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). It is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317 "[A] court 'should also consider the patent's prosecution history, if it is in evidence.'" *Id.* (quoting *Markman*, 52 F.3d at 980).

24. "[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." *Bell Commc'ns Research, Inc. v. VitaLink Commc'ns Corp.*, 55 F.3d 615 (Fed. Cir. 1995) (citations omitted). "[T]erms appearing in a preamble may be deemed limitations of a claim when they give

meaning to the claim and properly define the invention." *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994).

25. "Although no 'litmus test' exists as to what effect should be accorded to words contained in a preamble, review of a patent in its entirety should be made to determine whether the inventors intended such language to represent an additional structural limitation or mere introductory language." *Id.* "The effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (holding that a preamble reciting "an optical waveguide" was limiting as to the specific type of waveguide taught by the specification, and not to any type, as would be the case without construing the preamble as a limitation). "Whether a preamble of intended purpose constitutes a limitation to the claim is, as has long been established, a matter to be determined on the facts of each case in view of the claimed invention as a whole." *In re Stencel*, 828 F.2d 751,754 (Fed. Cir. 1987).

26. "'In considering whether a preamble limits a claim, the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim.'" *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1375 (Fed.

Cir. 2008) (*quoting On Demand Mach. Corp. v. Ingram Indus.*, 442 F.3d 1331, 1343 (Fed. Cir. 2006)). "[W]hen reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d at 808. Conversely, "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention," the preamble is not limiting. *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

27. Having heard oral argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction, the court construes the disputed claim language consistent with the tenets of claim construction set forth by the Unites States Court of Appeals for the Federal Circuit in *Phillips*, as follows:

2. Improving the hemodynamic efficiency of a heart

28. The parties dispute whether the preambles of independent claims 15 and 19 of the '119 patent constitute limitations and, if so, their proper construction. The preambles of claims 15 and 19 are identical and recite: "A method for improving the hemodynamic efficiency of a heart comprising the steps of: . . . ." At the very outset, the specification of the '119 patent defines an objective of the invention as "a method for increasing the cardiac output of a patient suffering from congestive heart failure," and

points to this objective to distinguish over the prior art.[4] ('119 patent at col. 1:18-22) It is evident from the specification that the invention exists in the context of improving the pumping ability of a heart that is in a state of (congestive) heart failure[5] and, thus, the preambles give meaning to the claims and properly define the invention. The court concludes that the preambles of claims 15 and 19 are limiting, and mean improving the heart's pumping ability for treatment of congestive heart failure. This construction is consistent with the specification: col. 1:18-22; col. 2:28-33; col. 3:12-15, 32-51; col. 4:23-27.

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[4] Although Funke does teach the concept of simultaneous stimulation of a plurality of spaced electrodes, he **does not disclose** its specific use as a method of **improving the cardiac output of patients suffering from congestive heart failure**."('119 patent at col. 2:28-33) (emphasis added)

[5] The specification teaches:

> The method of the present invention involves a procedure for pacing of the heart in a particular way so as to improve its contraction pattern, and thereby **augment the movement of blood through the heart**. Patients suffering from severe congestive **heart failure**, which is found not to respond well to conventional drug therapy and to have a conduction defect in the ventricle resulting in a widen [sic] Q-R-S complex have been aided by a pacing regimen in which stimulating pulses are simultaneously applied to both ventricles by way of a demand pacemaker or asynchronous pacemaker.
>
> It is theorized that a considerable part of the **hemodynamic impairment** in refractory congestive **heart failure** with conduction defects is due to an incoordinate contraction of the heart, so that a part of the heart muscle contracts and balloons out the part that is not contracting. When the latter area of the heart muscle does finally contract, the former has relaxed, so that a large part of the blood volume is merely shunted back and forth within the heart rather than being ejected as would happen with a more coordinate contraction pattern.

('119 patent at col. 3:32-51) (emphasis added)

3. Bi-ventricular pacemaker

29. The preambles of independent claim 25 and of dependent claim 26 of the '119 patent recite, "[a] bi-ventricular pacemaker . . . ." Plaintiff argues that this phrase "merely describes the purpose of claims 25 and 26." (D.I. 147 at 10) Although admitting that these claims require the capability to stimulate two ventricles, plaintiff argues that the language of the claim body alone, without consideration of the preamble, expressly creates this limitation.[6] Claim 25 recites:

> A bi-ventricular pacemaker comprising:
> **detecting means for detecting** a cardiac signal resulting from a **contraction of a first ventricle**;
> **stimulating means for effecting** immediate and unconditional **contraction of a second ventricle** in response to the

---

[6] "[T]he express language of the claims (without consideration of the preamble) calls for an apparatus for stimulating or pacing the two ventricles." (D.I. 147 at 10)

> detected cardiac signal, thereby effecting simultaneous contraction of both ventricles.

('119 patent at 11:1-7) (emphasis added)

30. Excluding the preamble, claim 25 discloses stimulating means for only one ventricle, the second. It is the preamble, with its term "bi-ventricular pacemaker," that describes structure capable of stimulating two ventricles. ('119 patent at col. 3:39-55, 6:13-22) Therefore, the court finds that the preamble of claim 25 contains a structural limitation that is not present in the body of the claim and concludes that the preamble of claim 25 constitutes a limitation. A bi-ventricular pacemaker, as used in the preamble of claim 25, means a device capable of providing stimulation to either one or both ventricles to effect a coordinated contraction thereof for the treatment of congestive heart failure. This construction is consistent with the specification: col. 3:32-4:26, col. 6:3-14, col. 7:17-20. Due to its dependency on claim 25, the preamble to claim 26 is similarly construed.

C. Infringement

1. Legal standard

31. To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents. *See Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336

(Fed. Cir. 2001). To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). Significant to the case at bar, if an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989).

32. To prove infringement by the doctrine of equivalents, a patentee must provide "particularized testimony and linking argument" as to the "insubstantiality of the differences" between the claimed invention and the accused product, or with respect to the function/way/result test. *See Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996).

33. Establishing the literal infringement of a means-plus-function limitation "requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999). A patentee may show structural equivalence "if the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the

corresponding structure described in the specification." *Id.* The *Odetics* court differentiated between the "similar analysis" of equivalents under the doctrine of equivalents and 35 U.S.C. § 112, ¶ 6, noting that a component by component analysis is not required to establish structural equivalence in the latter. *Id.* Indeed, such an analysis would be improper to the extent that

> [t]he individual components, if any, of an overall structure that corresponds to the claimed function are not claim limitations. Rather, the claim limitation is the overall structure corresponding to the claimed function.
>
> . . . The appropriate degree of specificity is provided by the statute itself; the relevant structure is that which "corresponds" to the claimed function. Further deconstruction or parsing is incorrect.

Id. at 1268 (internal citations omitted). Conversely, the relevant structure does not include "structure 'unrelated to the recited function' disclosed in the patent . . . ." *Id.* (*citing Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus.*, 145 F.3d 1303, 1308 (Fed. Cir. 1998)).

2. Burden of proof

34. The parties dispute which side has the burden to prove infringement at trial. Plaintiff argues that the burden is always on the patentee (defendants). (D.I. 193 at 7-9) Defendants assert that

the burden of proof was always on Medtronic as plaintiff, and argue three theories in support thereof. First, defendants argue that the Lilly agreement and the LTA provide that Medtronic must file a declaratory judgment action in order to challenge infringement, and that "the plaintiff usually has the burden of proof." (D.I. 247 at 38) Second, defendants argue that, due to these provisions, the case law cited by plaintiff is inapposite. (*Id.* at 38-39) Finally, defendants point to this court's guidelines as to post-trial briefing, establishing that the party having the burden of proof on an issue is usually permitted both an opening brief and a reply brief, whereas the opposing party is usually limited to an answering brief. (*Id.* at 39) Defendants allege that "Medtronic has taken the unusual position that it does not have the burden of proof but it is entitled to both open and reply on [the issue of infringement]." (*Id.*)

35. "The burden is always on the patentee to show infringement." *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) (*citing Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir.1984)). "Neither [the patentee's] burden to prove infringement nor [the accused infringer's] burden to prove invalidity, both ultimate burdens of persuasion, ever shifts to the other party - the risk of decisional uncertainty stays on the proponent of the proposition." *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008) (*citing Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1574 (Fed. Cir.

1985); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)).

36. As the parties asserting infringement, defendants bear the burden of proof by a preponderance of the evidence. *See Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569 (Fed. Cir. 1991) (*citing Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361 (Fed. Cir. 1983)).

3. Sufficiency of evidence

37. Plaintiff asserts that defendants' evidence of infringement is insufficient. (D.I. 193 at 9-10) During pre-trial proceedings, plaintiff requested that the court preclude Dr. Berger, defendants' expert on infringement, from testifying because "he failed to map every element of each asserted claim against the accused Medtronic devices in his expert report." (D.I. 189 at 327:4-5; D.I. 193 at 9) (*citing* D.I. 177-2 at 25; D.I. 255 at 116:11-120:3) Pursuant to the court's order of January 22, 2010 (D.I. 185), plaintiff again raised this issue during trial. (D.I. 189 at 472:2-474:11) The court, at the behest of the parties, reserved judgment on this issue pending post-trial briefing, allowing supplementation of the record. (*Id.*) In essence, plaintiff has raised a *Daubert* challenge, claiming that, in opining on infringement, Dr. Berger failed to apply reliable principles and methods to the facts of the case. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

a. Legal standard

38. The Supreme Court in *Daubert* made clear that courts have to play a gatekeeping role with respect to experts. *Daubert*, 509 U.S. at 113. According to the Supreme Court, Rule 702 of the Federal Rules of Evidence[7] is the primary locus of the gatekeeping role. Pursuant to Rule 702, a party can offer testimony of an expert witness at trial so long as the expert is qualified, the methodology the expert uses is reliable, and the opinion fits the facts of the case. *See Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000). A trial judge, then, is tasked with being a "'gatekeeper' to ensure that 'any and all expert testimony is not only relevant, but also reliable.'" *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008).

39. As recognized by the United States Court of Appeals for the Third Circuit, while an expert's methodology is required to pass muster under Rule 702, the data underlying the expert's

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[7] Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. § 702.

opinion must pass muster under Rules 104[8] and 703.[9] More specifically, the Third Circuit in *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717 (3d Cir. 1994), made clear "that it is the judge who makes the determination of reasonable reliance, and that for the judge to make the factual determination under Rule 104(a) that an expert is basing his or her opinion on a type of data reasonably relied upon by experts, the judge must conduct an independent evaluation into reasonableness." *Id.* at 748. The Third Circuit concluded in *In re Paoli* that, because the policy considerations underlying the rules of evidence are the same, the "reliability requirement" for admission under Rules 104, 702 and 703 should be the same "there must be good grounds on which to find the data reliable." *Id.*

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[8] Rule 104 provides:

> (a) **Questions of admissibility generally.** Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b) . . . .
>
> (b) **Relevance conditioned on fact.** When the relevance of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to, the introduction of evidence sufficient to support a finding of the fulfillment of the condition.

Fed. R. Evid. § 104.

[9] Rule 703 provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted[.]

Fed. R. Evid. § 703.

b. Literal infringement

40. Having determined that defendants, as patentees, have the burden to prove infringement the court recognizes at the outset of its discussion that there are litigation efficiencies in narrowing the issues to be resolved at trial. Therefore, if only certain limitations are in dispute, it makes sense to limit the presentation of evidence to such limitations. In this case, however, it is unclear from the record that there was an agreement among the parties to narrow the issues for trial. Aside from citing to an interrogatory response (DTX-71), it would appear that defendants relied primarily on their burden-shifting view of the case,[10] thus leaving the court

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[10] Defendants assert that they served an interrogatory on plaintiff, requiring plaintiff to identify each non-infringement assertion. (D.I. 247 at 35-36) Continuing their position that plaintiff had the burden of proof, defendants argue that,

> [s]ince Medtronic is the plaintiff in this action, Dr. Love's non-infringement expert report came before Dr. Berger's responsive infringement expert report. While Dr. Berger's expert report was primarily directed to each of Dr. Love's non-infringement assertions, Dr. Berger did cover all the elements of the asserted claims even though he did not repeatedly point out for each claim the undisputed presence of an element such as a pulse generator or a sense amplifier.

Footnote continued on next page . . .

between a rock (the way the parties chose to litigate this case) and a hard place (the court's responsibility to make an infringement determination based on appropriate evidence). Because plaintiff has asserted consistently that Dr. Berger failed to conduct an appropriate infringement analysis in his expert report, through his deposition and at trial, and because there is no affirmative evidence excusing Dr. Berger from this responsibility, the court will review the record to test the sufficiency of defendants' infringement analysis in this regard.

41. In its post-trial brief, plaintiff points to Dr. Berger's deposition testimony in support of its argument that "his expert report did not map every element of each asserted claim against each accused product."

> Q. Okay. And you understand that in undertaking an infringement analysis what you do is map each element of the asserted claim against the accused products; right?
> A. Correct.
> Q. Okay. In this case you did not do that for each limitation of the asserted claims; correct?
> A. I believe I did do that.

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footnote continued from prior page

> Also, after Medtronic had identified its non-infringement assertions which formed the basis for its declaratory judgment complaint, there was no need for Dr. Berger to concentrate on claim elements that Medtronic did not dispute.

(*Id.* at 36).

> Q. Okay. Well let's take a look at your report. As an example if we could turn to page 56, and section O of your report is dealing with the '897 patent, Claim 217. Do you see that?
> A. Yes.
> Q. Okay. And what follows is your analysis with respect to that claim; correct?
> A. I believe so, yes.
> Q. Okay. And in fact there are certain limitations in Claim 217 for which you did not map it to the accused products; correct, doctor?
> A. Let me read the
> Q. Sure.
> A. - section. (Witness reviewing exhibit.) Well in this section here in the - in the area of this report it does not list my opinions on each of the claims limitations, correct.
> Q. And in fact what you did, doctor, was respond to certain limitations that were addressed in the report of Dr. Love; correct?
> A. I believe that's -- I believe that was the philosophy that I took here, yes.
> Q. Okay. So you didn't in fact independently map each asserted limitation onto the accused devices; correct, doctor?
> A. In this - In this report that's correct

(D.I. 193 at 910) (*citing* D.I. 193, ex. A at 7:11-8:21)

42. Plaintiff supplemented the record with a video clip on CD media (*id.*, ex. B) purporting to show that "Dr. Berger's admissions were not 'off the cuff' or made under time restraints. Dr. Berger carefully and deliberately reviewed his expert report

for seven minutes before admitting that he failed to map the claims to the products." (D.I. 193 at 10) Plaintiff further asserts that, "[i]n addition, in their original pre-trial submission of Exhibit 5 to the Joint Pretrial Order to Medtronic, [d]efendants admitted that Dr. Berger did not address each claim limitation, stating that 'Dr. Berger was not required to map every element of each claim.'" (*Id.*) (*citing id.*, ex. C at 2)

43. Dr. Berger's expert report on infringement (D.I. 148, ex. 2, "Berger report") covers combinations of 27 claims of two patents asserted against nine accused products, and comprises 72 pages. The Berger report does not contain or reference a typical infringement analysis chart whereby each element of each asserted claim is individually compared with each accused product. Plaintiff does not assert that such a chart is required to prove infringement, although it would have certainly aided the court's determination of whether Dr. Berger's analysis met the required standard. Instead, Dr. Berger provides only a narrative discussion of various claim limitations, organized to be responsive to Dr. Love's expert report on non-infringement. (D.I. 148, ex. 1)[11]

44. Dr. Berger's analysis of claim 15 of the '897 patent serves as an example of the issue at bar. That claim recites, as the first of three limitations

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[11] As can be observed by comparing the table of contents of each of the two reports.

after the preamble, "a sense amplifier to receive ventricular depolarization signals originating from a first ventricle." Dr. Berger's analysis of the entire claim is limited to a recitation of the full claim language, followed by:

> It is my opinion that each of Medtronic's cardiac resynchronization systems marketed under the names InSync, InSync II Marquis, InSync II Protect, InSync Sentry, InSync Maximo, Concerto, Consulta and Maximo II delivers a stimulating pulse to the ventricles in response to a ventricular sense for the reasons discussed above in Section V(A)(3) [sic], or does not operate substantially differently than a device that operates in this manner.

(D.I. 148, ex. 2 at 47-48, § VI(G)) Section VI(A)(3) (*id.* at 30-31), in turn, is a narrative analysis of claim 15 of the '119 patent relating to the limitation, "stimulating both ventricles . . . when a cardiac depolarization signal originating from a first ventricle is detected." The court is unable to locate any reference to the term "sense amplifier" in section VI(A)(3). Section VI(A)(3) has a further reference to unspecified preceding sections relating to the VVT mode and VSR feature. The court is also unable to locate any consideration of the "sense amplifier" limitation in preceding sections. Moreover, it is not incumbent on the court to do so.

45. Dr. Berger similarly performs his analysis of claims 54, 84, 86, 120, and 144 of the '897

patent and others. Only vague perfunctory language potentially covers the remaining elements of asserted claims. Defendants' argument that they need only address elements identified in plaintiff's response to its interrogatories or in Dr. Love's non-infringement report (collectively "non-infringement defense") is inapposite as it does not address the issue at bar, whether Dr. Berger's testimony lacks sufficient foundation.

46. The Berger report fails to demonstrate that Dr. Berger considered each limitation of each asserted claim in comparison to each accused product before rendering his infringement opinions.[12] Plaintiffs non-infringement defense, even if considered an admission, would not relieve Dr. Berger of this requirement absent affirmative evidence to this effect. There is no way to determine if "every limitation set forth in a claim is found in an accused product, exactly," without accounting for each limitation. Any such admission would merely render that task easier to accomplish. Defendants have failed to prove literal infringement by a preponderance of the evidence.

c. Doctrine of equivalents

47. Plaintiff contends that Dr. Berger's doctrine of equivalents analysis consists solely of

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[12] The court notes in this regard that an expert cannot testify at trial beyond the opinions offered in his/her expert report. In this case, Dr. Berger's trial testimony is no more illuminating than his report and lacks a proper foundation.

conclusory statements, and fails to provide particularized testimony and linking arguments required to sufficiently prove infringement under this doctrine. (D.I. 193 at 27-28) (*citing id.*, ex. D at 19-23, 23-26, 31-33, 34-35, 36-39)

48. Defendants' argument regarding doctrine of equivalents is subsumed in their term-by-term rebuttal to plaintiff's non-infringement defenses. (D.I. 247 at 34, ¶ 9) Defendants argue, for example, with respect to the term "contractions" and the doctrine of equivalents that

> Dr. Mower's invention is directed to resynchronization of the ventricles and not to any particular manner in which a contraction is sensed (by electrical or mechanical sensing). Therefore, the resynchronization would take place using either form of sensing. Accordingly, the difference would be "insubstantial." As explained by Dr. Berger, "[t]he difference would not be substantial at all. The purpose is the same, to detect when the atria are activated."

(D.I. 247 at 24) (*citing* D.I. 189 at 342:9-13; D.I. 192 at 983:7-18; D.I. 246, ex. D, D.I. 148, ex. 2, at 31-33)

49. The Federal Circuit has explained that its "prior cases stand for the proposition that mere generalized testimony as to equivalence is insufficient as a matter of law to support a [] verdict finding infringement under the doctrine of equivalents." *Comark Commc'ns, Inc. v. Harris*

Corp., 156 F.3d 1182 (Fed. Cir. 1998). "'Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice [to show infringement under the doctrine of equivalents].'" *Id.* (*quoting Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996)) (brackets retained) The Federal Circuit has also previously stated that "[t]he evidence and argument on the doctrine of equivalents cannot be merely subsumed in plaintiff's case of literal infringement. Rather, 'a patentee must prove substantial identity as to each of the function, way and result prongs of the doctrine of equivalents.'" *Id.* (*quoting Lear Siegler, Inc. v. Sealy Mattress Co.*, 873 F.2d 1422, 1425 (Fed. Cir.1989); *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1327 (Fed. Cir. 1991)) (brackets retained). "The thrust of these cases is to ensure that a [finder of fact] is provided with the proper evidentiary foundation from which it may permissibly conclude that a claim limitation has been met by an equivalent." *Id.*

50. "[W]hile infringement under the doctrine requires 'only' substantial identity, substantial identity must be proven with regard to all three elements of the doctrine specified in *Graver Tank*: function performed, means by which function is performed, and result achieved." *Lear Siegler*, 873 F.2d at 1425 (*citing Universal Gym Equip., Inc. v. ERWA Exercise Equip. Ltd.*, 827 F.2d 1542, 1548 (Fed. Cir. 1987)). "Absent the proper *Graver Tank* context, i.e., a showing of how plaintiff compares the

function, means, and result of its claimed invention with those of the accused device, a [finder of fact] is more or less put to sea without guiding charts when called upon to determine infringement under the doctrine." *Id.* at 1425-26.

51. There are numerous instances in his testimony where Dr. Berger declares equivalent structure by simply stating "[t]he difference would not be substantial at all. The purpose is the same . . . ,"or words of a very similar nature. (D.I. 189 at 342:9-13) (*see also id.* at 345:1-7, 348:3-5, 372:3-24, 373:13-17) Dr. Berger's testimony lacks sufficient foundation; his expert report reflects the same failure to execute a proper doctrine of equivalents analysis as his testimony. (*See, e.g.*, D.I. 148, ex. 2 at 19, 31, 33, 35, 48-50) Defendants have failed to show, by a preponderance of the evidence, that the accused products infringe the asserted claims of the reissue patents under the doctrine of equivalents.

D. Invalidity

52. Plaintiff frames its arguments regarding anticipation and obviousness by grouping claims according to pacemaker operational modes as follows: VOO - claim 308 of the '897 patent; VVI and VDI - claims 120, 217, 233, 288, 303, 315, 324-328 of the '897 patent; VVT - claims 15, 25, and 26 of the '119 patent and claims 15, 54, 84, 86, 144, 172, 201, and 311 of the '897 patent; VAT- claims 19 and 20 of the '119 patent; and VDD- claims 248 and 273 of the '897 patent.

1. Prior art

53. Plaintiff asserts that four alleged prior art references, either alone or in combination with each other or the state of the art, either anticipate or make obvious the asserted claims of the reissue patents: "Tyers"[13] (PTX-216); "Gibson"[14] (PTX-219); "Silva"[15] (PTX-269); and "Curtiss"[16] (PTX-217). Each of the four asserted prior art references ("asserted references") were before the examiner during prosecution of the '897 patent. (PTX-5 at MEDMIR0023011, 23017, 23018, 23148; '897 patent at [56]) Plaintiff argues that Silva renders VAT and VVT claims anticipated and/or obvious; that Gibson renders VVI and VDI claims anticipated and/or obvious; that Tyers renders VOO, VDD, and VAT claims obvious; and that Curtiss renders VVT claims obvious. (D.I. 193 at 42; D.I. 188 at 4:22-24; PTX-515)

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[13] Tyers, G. F. O., *Comparison of the effect on cardiac function of single-site and simultaneous multiple-site ventricular stimulation after A-V block*, The Journal of Thoracic and Cardiovascular Surgery, 59(2):211-217 (1970).

[14] Gibson, D. G., et al., *Effect of Changes in Ventricular Activation on Cardiac Haemodynamics in Man*, British Heart Journal 33:397-400 (1971).

[15] *Influence of the Location of Ventricular Electrical Stimulation on Cardiac Efficiency*, Experimental and Clinical Study, Doctoral Dissertation, Lorenzo Silva Melchor, Autonomous University of Madrid School of Medicine, Madrid (1987).

[16] Curtiss, E. I., et al., *Electrocardiographically Discrete Right and Left Ventricular QRS Complexes: A Case Report*, Journal of Electrocardiology, 20(2): 162-168 (1987)

a. The state of the art

54. Plaintiff argues that "the treatment of heart failure was not a 'new' use for biventricular pacing," and that "[p]acing for heart failure was known at least as early as the late 1950s." (D.I. 193 at 36) As proof of these statements, plaintiff proffers the testimony of its expert, Dr. Benditt, in this regard. In addition to the asserted references discussed below, Dr. Benditt recounts various disclosures of atrial-(uni-)ventricular pacing for complete heart block and for heart failure, permanent pacemaking for treatment of bradycardia, and uni-ventricular pacing to treat heart failure. (D.I. 188 at 87:5-109:6) One of Dr. Benditt's state of the art references did explore the use of bi-ventricular pacing to treat certain arrhthymias, not heart failure; even then the study concluded right atrial and right ventricular pacing was preferable to bi-ventricular pacing to correct the arrhythmias. (*Id.* at 109:24-110:4, 237:2-239:17) Dr. Benditt testified that persons of skill in the art were "aware of the difficulty of treating heart failure and that while single chamber ventricular pacing was helpful in some patients, it failed to be adequate in many other patients." (D.I. 188 at 107:5-9) Indeed, Dr. Benditt's testimony does establish that there was a long-felt need to better address heart failure, even with the then available single ventricle pacing. (D.I. 188 at 87:5-109:6) The court finds that, excluding the asserted references, which are discussed in more detail below, Dr. Benditt's testimony fails to establish that bi-ventricular pacing

for heart failure was known, or even that univentricular pacing was particularly successful in treating congestive heart failure.

b. Tyers

55. Tyers is a 1970 study of multi-site pacing in dogs with induced heart block (profound bradycardia) but normal ventricles. (D.I. 190 at 561:14-24, 563:9-10, 15-16) Tyers induced heart block by crushing the A-V node, eliminating intrinsic electrical stimulation of the ventricles, and making the dogs dependent on extrinsic stimulation to sustain life. (*Id.* at 561:16-19) Tyers experimented with using 1, 2, 3, and 4 simultaneous ventricular pacing sites. (PTX-216 at MEDMIR0007199) The results showed that "tri-site" stimulation, with one electrode on the left ventricle and two on the right ventricle, provided a highly significant increase over stimulation of the left ventricle alone. (*Id.*) In contrast, stimulation of two sites, with one electrode on each ventricle, provided "no significant alteration of cardiac function." (*Id.* at MEDMIR0007199-200)

c. Gibson

56. Gibson is a 1971 study of the impact of various pacing locations in postoperative patients having undergone valve replacement. (PTX-219 at MEDMIR0001055). Of the six patients included in the study, five were in sinus rhythm and one was in atrial fibrillation. (*Id.* at 398, table I) The particular device implanted was a Starr-Edwards prosthesis, an early valve that would allow one way flow of blood,

comprising a birdcage-like container enclosing a ball. (D.I. 190 at 550:6-10) With the ball seated at the inlet end of the cage, the valve is sealed and back flow is prevented. (*Id.*) A characteristic property of the Starr-Edwards valve is that the ball makes a loud clicking sound as it contacts the end of the cage. (*Id.*) Gibson discloses a shortened ball travel time, based on timing of the clicks, when pacing is done to both ventricles as opposed to a single ventricle. (*Id.* at 550:20-23) Notwithstanding the shortened ball travel time, Gibson concluded that "the change . . . from single to bi-ventricular pacing was associated with no consistent alteration in either arterial pressure or cardiac output." (PTX-219 at MEDMIR0001058) Instead, Gibson suggests that "it is possible that more conspicuous changes could be obtained by variation in the numbers, position, or sequence of activation of ventricular electrodes" (*Id.*)

d. Silva

57. Silva is a 1987 doctoral dissertation written at the Autonomous University of Madrid. Medtronic and defendants dispute whether Silva meets the requirements of a "printed publication" under 35 U.S.C. § 102.

(1) Legal standard

58. Whether a reference is a "printed publication," under 35 U.S.C. § 102, is a "legal determination based on underlying issues of fact." *In re Hall*, 781 F.2d 897, 898 (Fed. Cir. 1986). "A reference is a 'printed publication' within the

meaning of section 102(b) if it was 'available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, [could] locate it.'" *Am. Stock Exch., LLC v. Mopex, Inc.*, 250 F. Supp. 2d 323, 328 (S.D.N.Y. 2003) (*citing In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1568 (Fed. Cir. 1988)) (brackets retained). "'Accessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to. If accessibility is proved, there is no requirement to show that particular members of the public actually received the information." *Id.* at 328-29. "[C]ompetent evidence of [] general library practice may be relied upon to establish an approximate time when a thesis became accessible." *In re Hall*, 781 F.2d at 897.

(2) Public access to Silva

59. To support their respective positions, both parties point to deposition testimony of the librarian who indexed, catalogued and shelved the thesis, Ms. Barredo-Sobrino ("librarian"). (D.I. 246, ex. I at 37:20-40:5) The librarian was originally deposed on June 30, 2007 ("2007 deposition"), during the St. Jude litigation, to which Medtronic was not a party. (D.I. 246, ex. J) She was again deposed on December 14, 2009 ("2009 deposition"). (D.I. 246, ex. I) Both depositions required the services of an interpreter.

60. Plaintiff argues that the librarian's testimony establishes that, based on the library's

normal business procedures, Silva was submitted to the library, cataloged, and available to the public no later than April1988. (D.I. 193 at 59) (*citing* 2007 deposition at 61, 64-78, 142-143)

61. Defendants assert that, while "[t]he reading room where the card catalogue was located was apparently open to the public . . . the thesis was located in the stacks, which were not open to the public, [that required one] to pass through a 'control point' to access doctoral theses." (D.I. 247 at 59) (*citing* 2007 deposition at 17:5-14) Defendants further assert that individuals permitted to pass through this control point were members of the university community, whereas other doctors could request access to a doctoral thesis only by first providing "accreditation" and a reason for consulting the thesis. (*Id.*) (*citing* 2007 deposition at 16:14-22, 39:16-40:11)

62. The librarian testified that a doctor not affiliated with the university who desired access to a doctoral thesis would have to "[first] identify himself with his official medical identification as a doctor of Spain [and then] fill out a form indicating the reason for his consultation." (2007 deposition at 39:16-40:3) It was possible for a non-Spanish doctor to "consult" a doctoral thesis by showing a passport in addition to the other requirements. (*Id.* at 40:4-8) Such consultation was restricted to the confines of the public reading room; the thesis could not be loaned out. (*Id.* at 40:8-11) Under such circumstances, provision was made for appropriate time to review the thesis and take notes. (*Id.* at 40:8-15) Non-

Spanish doctors had, in fact, consulted doctoral theses in the reading room in this manner. (*Id.* at 40:16-18) The librarian **did not testify** that any group or person was or would have been denied the opportunity to consult any doctoral thesis, including Silva.

63. Defendants argue that there is no clear and convincing evidence that "anyone not a member of the university family had access to the stacks where the doctoral theses were located." (D.I. 247 at 59) Defendants conflate access to the room where a doctoral thesis was kept with access to the thesis itself. Only access to the thesis is required. Moreover, it is not necessary to show that the thesis was actually accessed by anyone. *See Am. Stock Exch., LLC*, 250 F. Supp. 2d at 328. Although defendants argue there was no proof that either the reason for consultation or the accreditation of a Spanish or foreign doctor would be approved, there is no evidence of record that approval was required. (D.I. 247 at 59) Instead, the record shows that sufficient access was granted to Spanish and non-Spanish doctors, as well as to the university community. The court concludes that Silva qualifies as a printed publication under 35 U.S.C. § 102, and was publicly available no later than April1988. The '688 patent issued from an application filed on January 23, 1989, and no earlier priority date is claimed. ('688 patent at [22]) Silva qualifies as prior art to the '688 patent and the reissue patents.

(3) Silva as prior art

64. Silva disclosed a study of the impact of various pacing locations in the hearts of healthy dogs and postoperative patients. (D.I. 190 at 556:21-560:24; PTX-269 at MEDMIR0006892) The selection criteria for patients included in the study were: (1) a stable (normal) sinus rhythm; (2) no atrioventricular conduction disorders or bundle branch blocks on the 12-lead peripheral electrocardiogram; (3) an ejection fraction greater than 0.50 (normal left ventricular function), evaluated by angiogram; and (4) no akinetic, dyskinetic or hypokinetic areas after performance of the angiogram. (PTX 269 at MEDMIR0006953; D.I. 190 at 630:18-632:13) In the actual study populations, both the dogs and patients were in sinus rhythm. (PTX-269 at MEDMIR0006937, 6953) All ten patients were without bundle branch blocks or conduction abnormalities. (*Id.* at MEDMIR0006953) Of the ten patients, seven had "coronary artery disease and maintained ventricular function," and three "suffered from valve disease." *Id.* "Coronary patients with prior myocardial necrosis were rejected even if ventricular function had been maintained." *Id.* Silva concluded that "[b]i-ventricular electrical stimulation in post-operative patients (VAT mode) is hemodynamically more favorable than that obtained from univentricular stimulation." (*Id.* at MEDMIR000702)

e. Curtiss

65. Curtiss is a 1987 case report of a single patient that presented with the extraordinarily unique condition of having two separate QRS complexes resulting in separate mechanical contractions of the left and right ventricles. (PTX-217 at MEDMIR0008797, 8802) The patient in Curtiss was treated experimentally by pacing the left ventricle, triggered by sensing the right ventricle, wherein "[a] sense to pace interval of 50 msec. was selected since a therapeutic alternative was implantation of a modified universal pacemaker and the shortest sense to pace interval in the available units was 50 msec." (*Id.* at MEDMIR0008801) Curtiss reported that, hemodynamically, triggered left ventricular pacing was associated with a 24% rise in cardiac output. (*Id.*) In notational terms, triggered left ventricular pacing would be classified as VVT mode.

2. Anticipation

a. Legal standard

66. Under 35 U.S.C. § 102(a), "a person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."

67. A claim is anticipated only if each and every limitation as set forth in the claim is found,

either expressly or inherently described, in a single prior art reference. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

> [A]nticipation requires that each limitation of a claim must be found in a single reference. Although [the Federal Circuit has] permitted the use of additional references to confirm the contents of the allegedly anticipating reference, . . . we have made clear that anticipation does not permit an additional reference to supply a missing claim limitation.

Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1335 (Fed. Cir. 2002). That is, additional references may be used only to shed light on what a prior art reference would have meant to those skilled in the art at that time, not for a specific teaching, as this would be indicative of an attempt to improperly "combine the teachings of the references to build an anticipation." *Studiengesellschaft Kohle, m.b.H. v. Dart Industries, Inc.*, 726 F.2d 724, 727 (Fed. Cir. 1984).

68. A single prior art reference may expressly anticipate a claim where the reference explicitly discloses each and every claim limitation. However, the prior art need not be *ipsissimis verbis* (i.e., use identical words as those recited in the claims) to be expressly anticipating. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984).

69. A single prior art reference also may anticipate a claim where one of ordinary skill in the art would have understood each and every claim limitation to have been disclosed inherently in the reference. *Continental Can Co. USA Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). The Federal Circuit has explained that an inherent limitation is one that is necessarily present and not one that may be established by probabilities or possibilities. *Id.* That is, "the mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* "[I]nherency operates to anticipate entire inventions as well as single limitations within an invention." *Schering Corp. v. Geneva Pharms. Inc.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). The recognition of an inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation. *Id.* at 1377.

70. An anticipation inquiry involves two steps. First, the court must construe the claims of the patent in suit as a matter of law. *Key Pharms. v. Hercon Lab. Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998). Second, the finder of fact must compare the construed claims against the prior art to determine whether the prior art discloses the claimed invention. *Id.*

b. Silva and the VAT and VVT claims[9]

71. Each of the VAT and VVT claims[10] require either: (1) "improving the pumping ability of a heart that is in a state of congestive heart failure," by "effecting a coordinated contraction of both ventricles;"[11] (2) "a device capable of providing stimulation to both ventricles to effect a coordinated contraction thereof for the treatment of congestive heart failure;"[12] or (3) are directed to devices for treating heart failure and methods for improving the pumping ability of a heart suffering from heart failure.[13]

72. Plaintiff argues that Silva anticipates the VAT and VVT claims of the reissue patents, both triggered modes, by disclosing triggered, bi-ventricular pacing. (D.I. 193 at 51; PTX-515) Plaintiff further argues that Silva "clearly teaches that pacing both ventricles would be beneficial to patients in heart failure." (D.I. 193 at 40) (*citing* D.I. 188 at

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[9] Claims 15, 19, 20, 25 and 26 of the '119 patent and claims 15, 54, 84, 86, 144, 172, 201 and 311 of the '897 patent.

[10] As construed by the court with respect to asserted claims of the '119 patent.

[11] Claims 15, 19, and 20 of the '119 patent.

[12] Claims 25 and 26 of the '119 patent.

[13] Claims 15, 54, 84, 86, 144, 172, 201 and 311 of the '897 patent.

146:22-147:6; PTX-269 at 126; PTX-529 at 10; D.I. 188 at 145:4-14; PTX-269 at 120; PTX-529 at 8)

73. The parties disagree as to the nature of the patients included in the Silva study and as to the results. Plaintiff, relying on the testimony of its expert, Dr. Benditt, asserts "in 1988, Silva reported that bi-ventricular pacing was a better way to treat postoperative patients" and that the patients included those with "class II heart failure symptoms." (D.I. 193 at 39; D.I. 188 at 123:17-19). Defendants argue that Silva did not address any subjects that were in heart failure or had uncoordinated contraction of the ventricles. (D.I. 247 at 50) Instead, defendants assert that Silva was an attempt "to see which [pacing] site might be best and most closely approach that during sinus rhythm." (D.I. 190 at 557:8-9) Defendants further argue that "Silva determined that the patients would have been better off, hemodynamically, with no pacing at all." (D.I. 247 at 50) (*citing* D.I. 190 at 559:16-560:9; DTX-203 at DDX-115, DDX-11)

74. To anticipate the VAT and VVT claims, each and every limitation must be expressly or inherently described in a single prior art reference. Plaintiff argues that treatment of heart failure is an inherent property of bi-ventricular pacing. (D.I. 193 at 35) Inherency may not be established by probabilities or possibilities. *See Continental Can*, 948 F.2d at 1268. In its non-infringement argument, plaintiff argued that "approximately 30% of patients with CRT devices are 'non-responders,' meaning their hearts do not respond to the devices, and their

hemodynamic efficiency is not improved." (D.I. 193 at 12 n.8) Plaintiff proffers no evidence that treatment of heart failure using bi-ventricular pacing, as construed by the court, is inherently disclosed in the prior art. Silva itself distinguishes the apparatus and method used in the study from implantable devices which are more highly constrained as to ventricular pacing sites, and further identifies these constraints as the probable reason that earlier studies did not focus on bi-ventricular stimulation. The court finds that Silva did not address patients who were in (congestive) heart failure, a limitation shared by all of the VAT and VVT claims; therefore, the court concludes that Silva does not anticipate the VAT and VVT claims.

c. Gibson and the VVI and VDI claims[14]

75. Each of the VVI and VDI claims include one of three forms of preamble: a "heart stimulating device for treating heart failure;" a "method for improving the pumping ability of a heart suffering from heart failure;" a "heart failure treatment device for improving the pumping ability of a heart suffering from heart failure." The record shows that the examiner considered these preambles to be limitations and a means for distinguishing the claims over the prior art. (PTX-5 at MEDMIR0023137, "Notice of Allowance") ("[T]he

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[14] Claims 120, 217-233, 288, 303, 315, and 324-28 of the '897 patent.

prior art does not show a heart stimulating device for treating heart failure, or improving hemodynamics, as set forth in the claims.")

76. Plaintiff does not dispute that these preambles constitute limitations. Instead, plaintiff argues that Gibson renders VVI and VDI claims of the '897 patent anticipated by disclosing a commercial pacemaker capable of bi-ventricular pacing in a demand or inhibited mode; a lead placed in the atrium; a Y adapter used to allow electrodes to be placed in the left and right ventricles; and a predetermined A-V delay period. (D.I. 193 at 46) Plaintiff admits that "the experimental conditions in Gibson did not require atrial sensing," and instead argues that "one skilled in the art knew that the pacemaker Gibson used had the capability for atrial sensing and for an A-V delay period." (*Id.*) Presumably, this is in regard to VDI mode, which requires atrial sensing in addition to ventricular sensing. Finally, plaintiff asserts that Gibson further taught that bi-ventricular pacing effected a coordinated contraction, and that defendants' expert, Dr. Platia, "admitted that the improvement Gibson observed was due to a more synchronous contraction because of bi-ventricular pacing." (D.I. 193 at 47) The improvement admitted to by Dr. Platia, however, was with reference to shortened ball travel time of the valve, at the onset of systole, and not to improvement in hemodynamic efficiency over the entire cardiac cycle. (D.I. 190 at 599:19-25; 600:16-601:9)

77. Relying on the testimony of its expert, Dr. Benditt, plaintiff further asserts that the patients in the Gibson study were suffering from heart failure. (D.I. 193, ex. E at ¶ 120) (*citing* D.I. 188 at 97:1-14, 99:2-100:9, 184:16-187:5). The referenced portions of Dr. Benditt's testimony show that his assertions of heart failure in the Gibson study were often tentative: "[Gibson] was dealing with abnormal hearts. These had all had aortic valve surgery, and their cardiac outputs were all low . . . . So these are not just normal hearts that he's playing around with. These were sick hearts who got aortic valve replacements for **presumably** failing to thrive." (D.I. 188 at 99:9-15) (emphasis added) "That's **typically** a heart failure scenario, and **he's implying** that this new pacing mode, biventricular pacing that he observed, **may be of value** there. But he's also appropriately saying that **more study is needed**." (D.I. 188 at 100:2-6) (emphasis added)

78. Defendants argue that Gibson does not address patients in heart failure, but rather valve disease. (D.I. 247 at 44-45) Defendants further argue that, while Gibson may disclose shortened ball travel time resulting from bi-ventricular pacing, it also discloses that there was no associated gain in hemodynamic efficiency. (D.I. 190 at 552:7-13; D.I. 247 at 45)

79. The court finds defendants' characterization of Gibson to be the more credible. Plaintiff has failed to prove, by clear and convincing evidence, that each and every limitation as set forth in the VVI and VDI claims is found, either expressly

or inherently described, in Gibson. Gibson does not disclose a "heart stimulating device for treating heart failure;" a "method for improving the pumping ability of a heart suffering from heart failure;" or a "heart failure treatment device for improving the pumping ability of a heart suffering from heart failure." Therefore, the court concludes that Gibson does not anticipate the VVI and VDI claims of the '897 patent.

3. Obviousness

a. Legal standard

80. "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). Obviousness is a question of law, which depends on several underlying factual inquiries.

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding

> the origin of the subject matter sought to be patented.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)).

81. "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 550 U.S. at 418. Likewise, a defendant asserting obviousness in view of a combination of references has the burden to show that a person of ordinary skill in the relevant field had a reason to combine the elements in the manner claimed. *Id.* at 418-19. The Supreme Court has emphasized the need for courts to value "common sense" over "rigid preventative rules" in determining whether a motivation to combine existed. *Id.* at 419-20. "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. In addition to showing that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, a defendant must also demonstrate that "such a person would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007). "Because patents are presumed to be valid, see 35 U.S.C. § 282, an alleged infringer seeking to invalidate a patent on obviousness grounds must establish its obviousness

by facts supported by clear and convincing evidence." *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 968 (Fed. Cir. 2006) (citation omitted).

b. Tyers and the VAT[15], VOO[16] and VDD[17] claims

82. Plaintiff argues that the VAT claims are rendered obvious by Tyers, asserting that "Tyers disclosed all of the limitations of claim 19--including sensing the atrium and stimulating both ventricles for effecting a coordinated contraction of the ventricles following an A-V delay period." (D.I. 193 at 53) To complete the argument, plaintiff points to Dr. Benditt's testimony that, "this is all standard pacemaker stuff even in 1989." (*Id.*) Plaintiff further asserts that "it was well known that a coronary sinus pacing lead could be placed to pace the left ventricle, as required by claim 20." (*Id.*) Plaintiff concludes by arguing that "[f]or all of these reasons, Tyers also anticipates and/or renders obvious claims 19 and 20 of the '119 patent." (*Id.*)

83. Defendants respond that "the dogs in the Tyers study did not have heart failure or weak contractions, they had complete heart block." Plaintiffs expert, Dr. Benditt, agrees:

> Q. And A-V block, is that a form of heart failure?

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[15] Claims 19 and 20 of the '119 patent.

[16] Claim 308 of the '897 patent.

[17] Claims 248 and 273 of the '897 patent.

> A. A-V block is actually just interruption of the depolarization sequence between the atria and the ventricle, also previously talked of as heart block.

(D.I. 188 at 92:19-22)

84. . The '119 patent, as discussed earlier, involved pacing of "both the right and left [ventricles] to thereby increase the hemodynamic efficiency of a patient experiencing congestive heart failure or weak contractions." The court construed claims 15 and 19 to include the limitation, "improving the heart's pumping ability for treatment of congestive heart failure." Claim 20 depends from claim 19 and, therefore, must include the same limitation. The dogs in Tyers did not have congestive heart failure or ventricles that were contracting in an incoordinate manner. Instead, the dogs had an induced total heart block. The court finds that Tyers lacks the above stated limitations, and concludes that Tyers does not anticipate the VAT claims.

85. Plaintiff argues that "Tyers taught that pacing both ventricles simultaneously resulted in a significant increase in blood pressure and cardiac output." In fact, Tyers did not find an improvement with bi-ventricular pacing when using only two leads. Improvement was not shown except with the addition of a third lead. Bi-ventricular pacing, in and of itself, did not result in an improvement.

86. The VOO and VDD claims each require pacing the left and right ventricles for "effecting of a

coordinated contraction of ventricles contracting in an incoordinate manner to improve the pumping ability of the heart suffering from heart failure." Plaintiff argues that Tyers, in combination with the knowledge of one of ordinary skill in the art, renders the VOO and VDD claims obvious. Here, plaintiff goes into more detail, identifying background references that contribute to the comparison of the limitations with the claims. Most of these references are to known pacing modes. Plaintiff also asserts that coronary sinus electrodes, for pacing the left ventricle, were well known. Plaintiff fails to address the limitations directed to heart failure, coordinated contraction of ventricles, and the reason to combine the references.

c. Gibson and the VVI[18] and VDI[19] claims

87. Plaintiff argues that Gibson, "along with the knowledge of one of skill in the art," renders the VVI and VDI claims obvious. (D.I. 193 at 47-48) Plaintiff points to the availability of the various pacing modes as proof of obviousness. (*Id.*) The court's discussion above, with respect to anticipation by Gibson, informs its analysis of obviousness in light of Gibson. Gibson is not directed toward treating patients with heart failure or discoordinate ventricles. Bi-ventricular stimulation, as tested by Gibson, did not result in improved hemodynamic

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[18] Claims 217, 233, 288, 303, 325, and 328 of the '897

[19] Claims 120, 315, 324, 326, and 327 of the '897 patent.

efficiency, thus teaching away from bi-ventricular pacing to improve hemodynamic efficiency.

d. Curtiss and the VVT claims[20]

88. All of the asserted claims of the '119 patent, as construed by the court, require both ventricles to be paced to effect coordinated or simultaneous contraction of both ventricles.[21] The specification of the '119 patent teaches that "ventricular contractions which occur with [sic] 5-10 milliseconds of each other result in sufficient hemodynamic efficiency so as to not require treatment. Hence, the delay window may be of this order of magnitude." ('119 patent at 6:23-26)

89. Plaintiff argues that "Curtiss disclosed detecting a depolarization of the right ventricle and immediately stimulating the left ventricle." In its non-infringement argument, plaintiff asserts that a delay of 1.25 msec. is not immediate as used within the context of the reissue patents. (D.I. 193 at 17) Plaintiff admits that Curtiss discloses only single ventricle pacing, but argues that "pacing both ventricles was well known and standard in the art, as described, for example, in Tyers." (D.I. 193 at 54) Plaintiff further argues that "Curtiss provides the

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[20] Claims 15, 25 and 26 of the '119 patent.

[21] Claims 15 and 19 require "stimulating both ventricles for effecting a coordinated contraction of both ventricles." Claim 20 depends from claim 19. Claim 25 requires a "bi-ventricular pacemaker" for "effecting simultaneous contraction of both ventricles." Claim 26 depends from claim 25.

motivation for one skilled in the art to use bi-ventricular pacing in conjunction with the teachings of Curtiss." (D.I. 193 at 54) Dr. Benditt testified that "[Curtiss] could have stimulated both ventricles, but it's kind of a waste of energy to stimulate both," thereby suggesting that Curtiss teaches away from bi-ventricular pacing. (D.I. 188 at 172:5-8)

90. Plaintiff also argues that Curtiss in light of Tyers renders claims 25 and 26 obvious. (*Id.* at 54) That two or more prior art references disclose, in combination, all limitations of a claim does not, by itself, establish obviousness. Plaintiff fails to show any reason why a person of skill in the art would combine Curtiss, an extraordinary case involving one patient with dual QRS complexes, and Tyers, a study in dogs with complete heart block.

91. Defendants argue that the patient in Curtiss did not exhibit the "broadened QRS complex associated with heart failure" but, rather, "two distinct QRS complexes" that had never been seen before, nor since. (D.I. 190 at 541:16-24) Defendants' validity expert, Dr. Platia, opined that "[i]t certainly wouldn't occur to me that pacing in such a heart would give us any useful information to be interpreted broadly," and that this unique case was unrelated to the reissue patents. (D.I. 190 at 541:25-542:4)

92. Plaintiff again fails to provide motivation to combine Curtiss with any other reference or the knowledge of one of ordinary skill in the art. Curtiss involved single ventricle pacing of a

single unique case, with a sense to pace interval of 50 msec. The reissue patents are directed to stimulating both ventricles effecting a coordinated contraction of the ventricles (within 5-10 msec.) for treating heart failure. The court finds that plaintiff has failed to show Curtiss, in combination with any other reference, renders the VVT claims obvious.

e. Silva and the VAT and VVT claims

93. As previously discussed, Silva does not anticipate the asserted claims of the '119 patent as it did not address patients in heart failure. Plaintiff argues that, "in 1988, Silva reported that bi-ventricular pacing was a better way to treat postoperative patients." (D.I. 193 at 39) Silva itself distinguished the post-operative context as being less restrictive than using an implantable device. (PTX-269 at MEDMIR0006936) ("[I]t is not possible to select the point(s) of ventricular stimulation due to the limitations imposed by the implantation technique.") Defendants argue that, "[a]s with the Tyers and Gibson studies, the Silva thesis was directed to determining the least bad place to pace the heart." (D.I. 247 at 50) (*citing* D.I. 190 at 557:10-13)

94. Under *KSR*, it is not necessary that the prior art be directed to solving the same problem. *KSR*, 550 U.S. at 402, 418. The case at bar is not one, however, where "one of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution

encompassed by the patent's claims." *Id.* at 419-20. There was unquestionably a problem, one of long-felt need. Plaintiff has failed, however, to demonstrate an obvious solution. The field of the reissue patents is a complex one, involving the highest level of skill, incremental experimentation, uncertainty, and concerns over efficacy and safety. Even plaintiff admits that the patented devices and methods have far less than a 100% chance of success in treating heart failure. Experimentation in this field is time consuming, difficult, expensive, and poses some level of risk.

95. While Silva disclosed that bi-ventricular stimulation was more favorable, hemodynamically, than single ventricle pacing, this does not necessarily suggest hemodynamic improvement in heart failure. The base ejection fraction of the patients in Silva was 0.555 ± 0.018 whereas, with bi-ventricular pacing, it decreased to 0.535 ± 0.018. (PTX-269 at MEDMIR000699) Although the ejection fraction was even lower for single ventricle pacing, it supports defendants' conclusion that Silva demonstrated bi-ventricular pacing was the least bad solution under the circumstances. (*Id.*) Further supporting defendants' position, Silva also found that, with all three experimental positions, there was "a widening of the QRS" although it was less pronounced in bi-ventricular pacing. (*Id.* at MEDMIR0006987)

96. The court finds defendants' characterization of the results of Silva to be the more persuasive. Plaintiff has failed to show, by clear and convincing evidence, that Silva, in view of the

knowledge of one of ordinary skill in the art or in combination with any other reference, renders the VAT and VVT claims obvious.

f. Secondary considerations

97. As discussed earlier, Dr. Benditt pointed to the long-felt unfulfilled need to treat heart failure. (D.I. 247 at 57) Plaintiff admits that Dr. Mower's invention is successful in treating heart failure in more than 60% of cases. (D.I. 189 at 301:10-11, 23-24, 302:2-4) While arguing that all of the components of a bi-ventricular pace maker were available prior to Dr. Mower's invention and such combination was obvious, Plaintiff fails to adequately account for the lack of success in addressing this long-felt need. Based on the foregoing, the court finds that, taken as a whole, the secondary considerations favor defendants and do not change the obviousness determination discussed above.

g. Conclusion

98. Plaintiffs arguments regarding obviousness are less than compelling, attempting only to demonstrate that limitations of the asserted claims can be found as disparate pieces in various combinations of the prior art. Dr. Benditt, plaintiff's invalidity expert, admitted that he failed to consider any apparent reason to combine references in

forming his opinions.[22] Moreover, many of the asserted references teach away from bi-ventricular pacing. Plaintiff has not demonstrated, by clear and convincing evidence, that the asserted claims of the reissue patents are invalidated on obviousness grounds.

E. Prosecution Laches

1. Legal standard

99. The doctrine of prosecution laches is an equitable defense to a charge of patent infringement that "'may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution' that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances." *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., LP*, 422 F.3d 1378, 1384-85 (Fed. Cir. 2005) ("Symbol Techs. II") (citation omitted). "[T]here are no strict time limitations for determining whether continued refiling of patent applications is a legitimate utilization of statutory provisions or an abuse of those provisions. The matter is to be decided as a matter of equity, subject to the discretion of a district court before which the issue is raised." *Id.* at 1385. A

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[22] Dr. Benditt in his deposition stated, "it would be obvious to somebody who was working in the field who was familiar with the literature that this would not be a particular stretch of the imagination. . . . what would lead me to . . . say, 'Oh, I'm going to combine X and Y,' I don't think we can give you an answer here." (D.I. 188 at 225:17-226:9)

finding of prosecution laches further requires " a finding of prejudice, as does any laches defense." *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 729 (Fed. Cir. 2010).

100. An applicant may attempt to obtain new claims directed to inventions that he or she believes are fully disclosed and supported in an earlier application. *See In re Bogese*, 303 F.3d 1362, 1369 (Fed Cir. 2002). This is distinguished from an applicant failing to further the prosecution of his or her application toward the issuance of any claims. *Id.* The Federal Circuit has made clear that

> there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.

Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988}.

2. Discussion

101. The original '688 patent, on which the reissue patents are based, was filed on January 23, 1989 and issued on May 29, 1990. The '119 patent resulted from a series of three continuation applications, the first of which was filed on May 29,

1992, and issued May 20, 2003. The '897 patent was filed on August 8, 2002 and issued on October 23, 2007.

102. Plaintiff argues that the claims of the '897 patent are unenforceable for prosecution laches. (D.I. 193 at 2) In support of this argument, plaintiff asserts that the application for the '119 patent "lingered in the patent office until 2003, over 14 years after the filing of [the] original '688 patent application." (*Id.* at 3) Plaintiff further asserts that during those 14 years, the market developed for CRT devices. (*Id.*) Plaintiff introduced its first CRT product in 2001. (*Id.*)

103. The evidence of record demonstrates that the delays in prosecution of the '119 patent were reasonable. (D.I. 247 at 10-11; PTX-7, PTX-8) The delays are documented in the file history as being caused by a withdrawal of allowability by the PTO and the PTO's twice losing the file. (*Id.*) Meanwhile, defendants diligently prosecuted the '119 patent seeking repeated status updates. (*Id.*)

104. Plaintiff further argues that, since the '119 patent did not cover commercially available devices, defendants filed a new reissue application a year after plaintiffs InSync product was released in 2001, in an attempt to obtain new claims to assert against their competitors. (*Id.*) This new reissue application resulted in issuance of the '897 patent. (*Id.*) Finally, plaintiff asserts that "Dr. Mower did nothing for over a decade after he first noticed the alleged errors in the '688 patent to ensure that these

additional 300 claims [of the '897 patent] were prosecuted."

105. Defendants counter that the '897 application was filed on August 8, 2002 after the PTO stated that the '119 claims were allowable. (D.I. 247 at 12; PTX-5) Prosecution consisted of three rejections and three responses, all within the statutory period. *Id.*

106. Plaintiff, relying on *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., LP*, 301 F. Supp. 2d 1147, 1157 (D. Nev. 2004) ("Symbol Techs. I") argues that the failure to prosecute all claims of a patent (or reissue patent) as soon as they are known constitutes prosecution laches. *In Symbol Techs. I*, the patentee had "effectively extended his patent monopoly by maintaining co-pendency for nearly forty years through continuation practice, and added new claims to cover commercial inventions in the market place years after his original patents had expired." *Id.* The court finds no such unreasonable or unexplained delay with respect to the reissue patents.

III. CONCLUSION

For the reasons discussed above, the court concludes that defendants have not proven, by a preponderance of the evidence, that plaintiff Medtronic infringes claims 15, 19, 20, 25, or 26 of the '119 patent, or claims 15, 54, 84, 86, 120, 144, 172, 201, 217, 233, 248, 273, 288, 303, 308, 311, 315, or 324-328 of the '897 patent. Plaintiff has failed to prove, by clear and convincing evidence, that the aforesaid claims are invalid as anticipated. Plaintiff has not demonstrated, by clear and convincing evidence, that the aforesaid claims are invalid as obvious. Plaintiff likewise has failed to establish, by clear and convincing evidence, that the reissue patents are unenforceable by reason of prosecution laches. An appropriate order shall issue.

APPENDIX C

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2011-1313, -1372

MEDTRONIC INC.,

Plaintiff-Cross Appellant,

v.

BOSTON SCIENTIFIC CORPORATION
and GUIDANT CORPORATION,

Defendants,

and

MIROWSKI FAMILY VENTURES, LLC,

Defendant-Appellant.

Appeals from the United States District Court for the District of Delaware
in case no. 07-CV-0823, Judge Sue L. Robinson.

ORDER

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Cross-Appellant, and a response thereto having been invited by the court and filed by the Appellant, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on December 21, 2012.

FOR THE COURT

/s/ Jan Horbaly
Jan Horbaly, Clerk

Dated: 12/14/2012

cc: **Arthur I. Neustadt**
Martin R. Lueck

MEDTRONIC V BOSTON SCIENTIFIC, 2011-1313, -1372
(DCT - 07-CV-0823)

OPPOSITION BRIEF

No. 12-1128

IN THE

Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

MIROWSKI FAMILY VENTURES, LLC.

Respondent,

and

BOSTON SCIENTIFIC CORPORATION and
GUIDANT CORPORATION

Respondents.

**On Petition for Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit**

BRIEF IN OPPOSITION

SIDNEY J. SILVER
SILVER, FREEDMAN &
TAFF, LLP
3299 K Street, N.W.
Washington, D.C. 20007
(202) 295-4500

ARTHUR I. NEUSTADT
Counsel of Record
THOMAS J. FISHER
JOHN F. PRESPER
OBLON, SPIVAK, MCCLELLAND,
MAIER & NEUSTADT, LLP
1940 Duke Street
Alexandria, VA 22314
(703) 413-3000
aneustadt@oblon.com

Counsel for Respondent
Mirowski Family Ventures, LLC

CORPORATE DISCLOSURE STATEMENT

Mirowski Family Ventures, LLC is a limited liability company that is not publicly traded. It has no parent corporation and no publicly held company owns 10% or more of its stock.

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BRIEF IN OPPOSITION

Respondent Mirowski Family Ventures, LLC ("MFV") respectfully submits this brief in opposition to Medtronic's petition for a writ of certiorari.

OVERVIEW

Medtronic asserts that the Federal Circuit's decision is inconsistent with this Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) and that this supposed inconsistency will result in a parade of horribles. However, there is no inconsistency, nor is there any parade of horribles.

MedImmune dealt with the not uncommon situation where the patent licensee (MedImmune) wished to challenge its liability to pay royalties for particular products, but it could not do so without running the risk that the patentee (Genentech) would regard the challenge as a breach of the license, and counterclaim for an injunction and damages. Accordingly, MedImmune continued to pay royalties. Because MedImmune continued to pay royalties, Genentech asserted that there was no justiciable controversy necessary to support declaratory judgment ("DJ") jurisdiction. The Federal Circuit agreed, but this Court disagreed, holding that MedImmune did not have to "bet the farm" to challenge its liability to pay royalties for particular products under the license. *Id.* at 134.

In the case at bar, Medtronic never had any *MedImmune* problem because the 1991 MFV-Medtronic license gave Medtronic the specific right to file a DJ action to challenge its obligation to pay royalties for particular products. Thus, unlike the situation in *MedImmune*, Medtronic never had to "bet the farm" to challenge its obligation to pay royalties under the license.

Pursuant to the license, Medtronic did file a DJ action asserting non-infringement (non-claim coverage since Medtronic remained a licensee and, therefore, could not be an infringer).[1] In the suit, Medtronic asserted that MFV had the burden to prove infringement (claim coverage). The district court agreed but the Federal Circuit reversed, holding that under the terms of the license, Medtronic had the responsibility of filing the declaratory judgment action, and it had the burden of proof because it was the only party in the suit requesting any relief. The Federal Circuit specifically noted that MFV merely desired to have the suit dismissed.

> The contract at issue here required MFV to identify products it believed were covered

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[1] 35 U.S.C. § 271(a) defines infringement as acting "without authority." As a licensee, Medtronic did not act "without authority." Similarly, both Medtronic and MFV agreed to the term in the pretrial order that - "the term 'infringement' is used in the LTA [litigation tolling agreement] to indicate claim coverage. Since Medtronic is a licensee, it cannot be an infringer." A2303. ("A___" refers to the joint appendix in the Federal Circuit appeal).

> by the contract [license]. After MFV identified those products, Medtronic was required to either pay royalties on them, or sue for declaratory judgment that the products were not covered. *Medtronic is unquestionably the party now requesting relief from the court*: it already has a license; it cannot be sued for infringement; *it is paying money into escrow; and it wants to stop.* In contrast, regarding the patents at issue here, MFV seeks nothing more than to be discharged from the suit and be permitted to continue the quiet enjoyment of its contract. (footnote omitted) *In other words, it is Medtronic and not MFV that is asking the court to disturb the status quo ante and to relieve it from a royalty obligation it believes it does not bear.* Consistent with the above, for the court to disturb the status quo ante, Medtronic must present evidence showing that it is entitled to such relief. *If neither party introduced any evidence regarding infringement or noninfringement there is no principled reason why Medtronic should receive the declaration of noninfringement it seeks.*

App. 12a-13a (emphasis added).

Thus, the Federal Circuit's decision is in no way inconsistent with *MedImmune*. It was the specific terms of the 1991 license that controlled and dictated the result. These terms permitted Medtronic to file the DJ action and precluded MFV from counterclaiming for an injunction and damages since Medtronic remained a licensee. The Federal Circuit's decision that Medtronic *under these specific terms* had the burden of proof is unremarkable and consistent with applicable precedent.

STATEMENT

A. Factual Background

The patents in suit, RE38,119 ("the '119 patent") and RE39,897 ("the '897 patent"), are directed to the field of cardiology and, more particularly, to cardiac resynchronization therapy ("CRT") for treating congestive heart failure. CRT was invented by Morton M. Mower, M.D.

Dr. Mower, a practicing cardiologist for many years, is as the district court stated "a renowned researcher in the cardiology field." A107. In the 1970s and while he was a practicing cardiologist, Dr. Mower worked with Dr. Mieczyslaw Mirowski at the Sinai Hospital of Baltimore to invent the first implantable cardioverter defibrillator ("ICD") which, since its introduction, has saved countless lives. A1479-81. For this work, Dr. Mower was inducted into the National Inventors Hall of Fame. A107; A1481. After his work on the ICD, and in the 1980s while still a practicing cardiologist, Dr. Mower turned his attention to the treatment of congestive heart failure, a condition more widespread than ventricular fibrillation for which the ICD was invented. Dr. Mower recognized that the ICD, despite its overwhelming success in saving lives, did not address the many lives lost each year from congestive heart failure. Dr. Mower also recognized that a patient could be saved by an ICD only to subsequently succumb to more prevalent chronic congestive heart failure. A1481-82.

In the late 1980s, Dr. Mower devised his cardiac resynchronization therapy for treating congestive heart failure. A1488-91. In the early 1990s, looking to have Guidant Corporation obtain FDA approval for his CRT treatment, Dr. Mower arranged for investigators to conduct trials of his treatment on patients suffering from congestive heart failure. A1491-93; A1496. Dr. Mower supplied modified pacemakers for use in the trials and they were subsequently implanted in eighteen patients.[2] A1493-97. The results of the trials were "excellent," even "amazing."

> [I]mmediately upon implanting the device, the patient starts to do very well. They feel better. They lose that ashen color. They were able to -- whereas before, they were confined to bed and a chair, they were able to walk and actually do exercise tests and things like that. And they mobilize fluid on their own. We have to cut back on the

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[2] Dr. Mower arranged for these trials to be done by Dr. Patricia Bakker, a cardiac surgeon in the Netherlands (15 patients), Dr. Leslie Saxon at UCLA (one patient) and Dr. Michael Gold at the University of Maryland (two patients). As a result of the trials, Guidant began an FDA trial that resulted in a market release for Guidant's CRT device. A1492-98.

> diuretic medicine so they don't get dehydrated. And echo[e]s of the heart show an improvement in the function.

A1495; A1498.

Dr. Mower's CRT treatment for congestive heart failure uses an implanted pacemaker to continuously coordinate the contractions of the left and right ventricles of the heart. A1488-89. Dr. Mower was familiar with pacemakers and their operation from his work as a practicing cardiologist. He determined that a conventional pacemaker could be modified so as to ensure a coordinated contraction of the left and right ventricles for each heartbeat. The modification involved adding a lead and electrode from the pacemaker to the left ventricle. A1494. Dr. Mower's treatment is so effective and beneficial that it has today become the standard of care for the treatment of advanced heart failure. A1499; A1525-26.

Medtronic's statements to physicians, prospective patients, and the public speak in no uncertain terms to the remarkable effectiveness of Dr. Mower's invention. Medtronic describes CRT as "*a revolutionary new approach* to managing heart failure," "*a proven treatment* for selected patients with ... ventricular dyssynchrony," and "designed to reduce symptoms and *improve cardiac function*." A2801 (emphasis added).

Medtronic also describes the benefits of Dr. Mower's CRT treatment as follows:

> Following a sensed atrial contraction or atrial-paced event, both ventricles are stimulated to synchronize their contraction. *The resulting ventricular resynchronization reduces mitral regurgitation and optimizes left ventricular filling, thereby improving cardiac function.*

A2702 (emphasis added).

> For those patients with heart failure who have electrical conduction problems of the heart, resynchronization therapy is intended to improve the heart's efficiency and increase blood flow to the body. Blood ejected from the heart is decreased in people who have heart failure, which is the reason they often experience symptoms such as fatigue, shortness of breath, and swelling (or edema) of the feet and ankles. *By improving blood flow, heart resynchronization therapy may reduce heart failure symptoms, improve quality of life and increase patients' ability to perform the tasks of daily living.*

A2902 (emphasis added).

B. The District Court's Decision

Pursuant to the 1991 license, Medtronic filed a DJ action against MFV in 2007. Medtronic asserted non-infringement (claim coverage since Medtronic was a licensee and could not infringe), invalidity and unenforceability. In accordance with the 1991 license, MFV filed no counterclaim for injunction or damages.

The trial was to the court and not to a jury. After a five day trial and post-trial briefing, the district court held against Medtronic on validity and enforceability, but against MFV on infringement (claim coverage), holding that MFV had the burden of proof on this issue and had not sustained this burden.

As to infringement (claim coverage), Medtronic asserted that MFV's expert Dr. Berger had not covered in his expert report each of the elements of the patent claims at issue. However, Medtronic declined to identify any element that Dr. Berger had supposedly not covered in his report. After post-trial briefing, and presumably reluctant to rule against MFV on this issue without identifying any missing element, the district court *sua sponte* made its own review, and concluded that Dr. Berger's report did not cover the "sense amplifier." On this basis, the district court then held that MFV had not sustained its supposed burden of proof.

This district court erred on this point for a number of reasons. First, Dr. Berger's report did include the sense amplifier. Second, most of the claims at issue in both the '119 and '897 patents did not recite a sense amplifier and, therefore, did not require its presence. Third, Medtronic's engineer Ms. Kleckner, who had helped design its CRT device testified at trial that Medtronic's devices did include the sense amplifier. Fourth, Medtronic had limited the infringement issues through discovery so as not to include the sense amplifier. Fifth, since MFV did not (and could not) counterclaim for infringement, Medtronic was the only party requesting any relief and, therefore, had the burden of proof.[3] Sixth, contrary to Medtronic's assertion (at 7) that "MFV did not offer any affirmative evidence of infringement," Dr. Berger's testimony at trial (and his expert report) applied each element of each claim at issue including the sense amplifier to each Medtronic CRT device.[4]

C. The Federal Circuit's Decision

The Federal Circuit addressed only the burden of proof issue as to infringement (claim coverage) and held that Medtronic, not MFV, had the burden of proof because Medtronic was the only party requesting relief.

> Medtronic is unquestionably the party now requesting relief from the court: it already has a license; *it cannot be sued for infringement; it is paying money into escrow; and it wants to stop.* In contrast, regarding the patents at issue here, *MFV seeks nothing more than to be discharged from the suit* and be permitted to continue the quiet enjoyment of its contract.

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[3] See MFV's opening (blue) brief before the Federal Circuit (filed July 13, 2011) at 39-60.

[4] *Id.* at 13-27

> (footnote omitted)"

App. 12a (emphasis added).

The Federal Circuit further held that it was Medtronic, not MFV, that sought to disturb the status quo.

> In other words, *it is Medtronic and not MFV that is asking the court to disturb the status quo ante* and to relieve it from a royalty obligation it believes it does not bear. Consistent with the above, *for the court to disturb the status quo ante, Medtronic must present evidence showing that it is entitled to such relief. If neither party introduced any evidence regarding infringement or noninfringement there is no principled reason why Medtronic should receive the declaration of noninfringement it seeks.*

Id. at 12a-13a (emphasis added).

The Federal Circuit relied upon this Court's precedent in holding that the party seeking relief, Medtronic, bears the burden of proving the allegations in its DJ complaint.

> Generally, *the party seeking relief bears the burden of proving the allegations in his complaint. See Schaffer ex rel. Schaffer v. Weast*, 546 U.S. 49, 56-57 (2005). "Perhaps the broadest and most accepted idea is that

> the person who seeks court action should justify the request ...." *Schaffer*, 546 U.S. at 56 (quoting C. Mueller & L. Kirkpatrick, *Evidence* § 3.1, p. 104 (3d ed. 2003)). "*The burdens of pleading and proof with regard to most facts have been and should be assigned to the plaintiff who generally seeks to change the present state of affairs and who therefore naturally should be expected to bear the risk of failure of proof or persuasion.*" *Id.* (quoting 2 J. Strong, *McCormick on Evidence* § 337, p. 412 (5th ed. 1999)).

Id. at 9a-10a (emphasis added).

The Federal Circuit further held that MFV did not have the burden of proof because it did not (and could not) counterclaim for infringement

> And in the customary declaratory judgment case, ... the declaratory judgment defendant must assert a counterclaim for infringement to avoid risking the loss of that claim forever. *See id.* *But this is not such a case. In this case, ... the continued existence of the license precludes the very infringement counterclaim that normally would impose the burden of proving infringement on the patentee. Here, Medtronic is shielded from any liability for infringement by its license. And MFV has not asserted a claim of infringement, nor could it because of the license.*

Id. at 12a (emphasis added).

The Federal Circuit further held that "the one claim for relief sought in this case" was the claim sought by Medtronic and it, not MFV, should bear the burden of proof on this claim.

> As noted, neither party here seeks money damages or an injunction based on patent infringement, which are the sorts of relief generally sought when a party seeks relief for patent infringement. *Instead, the one claim for relief sought in this case is the claim Medtronic asserts to be relieved from liability under the license by having a court declare the products in question to be noninfringing. Medtronic is the party seeking this relief and Medtronic must bear the burden of proving it is entitled to such relief.*

Id. at 14a (emphasis added).

To hold otherwise would allow licensees "to use *MedImmune's* shield as a sword."

> *A contrary result would allow licensees to use MedImmune's shield as a sword -- haling licensors into court and forcing them to assert and prove what had already been resolved by license.* Because the declaratory judgment plaintiff is the only party seeking the aid of the court in the circumstances presented here, that party

> must bear the burden of persuasion.

Id. (emphasis added).

The Federal Circuit pointed out that the result in this case was highly dependent upon "the limited circumstance" of the specific terms in the MFV-Medtronic license.

> Therefore, this court holds that in *the limited circumstance when an infringement counterclaim by a patentee is foreclosed by the continued existence of a license*, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion.

Id. (emphasis added).

REASONS FOR DENYING THE PETITION

I. Contrary to Medtronic's Assertion, the Federal Circuit's Decision is Consistent with this Court's Precedent and the Principles of Federal Civil Procedure.

Medtronic asserts (at 4) that MFV "accused products first marketed in 2004 of infringing patent claims first issued in 2003 and 2007, over a decade after the license was signed in 1991." However, Medtronic's chronology omits Medtronic's first DJ action against MFV in Delaware filed in 2003. The current case involves Medtronic's second generation

CRT products. The 2003 suit involved Medtronic's first generation CRT products. After a three-day bench trial in 2004, the district court held for MFV. *Medtronic, Inc. v Guidant Corp.*, 378 F.Supp.2d 503 (D. Del. 2005). The Federal Circuit affirmed. 465 F.3d 1360 (Fed. Cir. 2006). Medtronic then paid the royalties due for its first generation CRT products.

Throughout its petition, Medtronic assiduously ignores the dispositive fact that the 1991 license required Medtronic to file the DJ action (to be the plaintiff in the suit) and precluded MFV from counter-claiming for infringement (or requesting other relief) because Medtronic was still its licensee. Nowhere is this more apparent than in Medtronic's Question Presented (at i) where it fails to acknowledge that the terms of the license effectively controlled who had the burden of proof on claim coverage.

> The question presented is whether ... the licensee has the burden to prove that its products do not infringe the patent, or whether (as is the case in all other patent litigation, including other declaratory judgment actions), the patentee must prove infringement.

Medtronic's Question Presented is also incorrect in asserting that a patentee must prove infringement "in all ... patent litigation, including ... declaratory judgment actions." A patentee not asserting infringement has no obligation to prove what it does not assert.

Medtronic asserts (at 10) that there is supposedly a "fundamental principle of patent litigation that a patentee must prove infringement." However, a patentee need prove infringement only when it asserts it. There is no requirement for a patentee to prove infringement if it does not assert it, as is the case here.

Rather, the fundamental principle is as this Court held in *Schaffer v Weast*, 546 U.S. 49 (2005),

> We hold that *the burden lies, as it typically does, on the party seeking relief.*

Id. at 51 (emphasis added).

> [P]etitioners offered no persuasive reason to "depart from *the normal rule of allocating the burden to the party seeking relief.*" 377 F.3d 449, 453 (2004).

Id. at 55 (emphasis added).

> We therefore begin with *the ordinary default rule that plaintiffs bear the risk of failing to prove their claims.* McCormick § 337, at 412 ("The *burdens* of pleading and *proof* with regard to most facts have been and should be *assigned to the plaintiff who generally seeks to change the present state of affairs and who therefore naturally should be expected to bear the risk of failure of proof or persuasion*"); C. Mueller & L. Kirkpatrick, Evidence § 3.1, p 104 (3d

> ed. 2003) ("Perhaps the broadest and most accepted idea is that *the person who seeks court action should justify the request, which means that the plaintiffs bear the burdens on the elements in their claims*").

Id. at 56 (emphasis added).

> [W]e have usually assumed without comment that *plaintiffs bear the burden of persuasion regarding the essential aspects of their claims.*

Id. at 57 (emphasis added).

> [W]e will conclude that *the burden of persuasion lies where it usually falls, upon the party seeking relief.*

Id. at 57-58 (emphasis added).

Medtronic asserts (at 10) that supposedly "[t]his Court has long held that when an issue of patent infringement is contested, it is the patentee, not the accused infringer, that bears the burden of proving infringement." Medtronic cites *R.R. Co. v. Mellon*, 104 U.S. 112, 119 (1891) and *Cammeyer v. Newton*, 94 U.S. 225, 231 (1877). However, in each case, the patentee asserted infringement against an accused infringer and, of course, had the burden of proof unlike in this case, where MFV did not assert infringement, and could not do so because Medtronic was a licensee who had not breached its license.

Medtronic asserts (at 12) that "this court has held (and the Federal Circuit recognized) that 'mere role reversal in a declaratory judgment action does not shift the burden.'" However, Medtronic is referring to a DJ action in which the patentee counterclaims for infringement. In such an instance, the patentee has the burden to prove infringement since it has asserted it. This is to be distinguished from the case at bar where MFV did not, and could not, assert infringement.

Medtronic asserts (at 13) that the Federal Circuit's decision "create[s] a gaping exception." However, the decision creates no such exception. Rather, Medtronic had the burden of proof on infringement (claim coverage) because, as held by the Federal Circuit,

> *[I]n the limited circumstance when an infringement counterclaim by a patentee is foreclosed by the continued existence of a license*, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion.

Id. at 14a (emphasis added).

Medtronic also asserts (at 13) that "[t]his case does not meaningfully differ from a traditional declaratory judgment action for noninfringement in response to a patentee's assertion of infringement" because MFV, pursuant to the license, advised Medtronic that there was claim coverage for

Medtronic's products. However, advising Medtronic as to infringement (claim coverage) does not amount to filing a counterclaim for infringement, as would be required for MFV to have any burden of proof. Medtronic is simply railing against the terms of its license, which it sought so that it could challenge liability without running the risk of breaching its license.

Medtronic also asserts (at 13) that it "began this action" because it did not want to "risk such serious consequences" as being "'ordered to pay treble damages and attorney's fees and ... enjoined from selling' its products." However, this belies the fact that Medtronic was a licensee, who had no such risk under the 1991 license, which permitted it to challenge liability without breaching its license.

Medtronic asserts (at 14) that the Federal Circuit was wrong when it said that MFV did not seek money damages because, according to Medtronic, "MFV seeks royalties from Medtronic." However, the Federal Circuit's statement that MFV did not seek money damages refers to the fact that MFV did not seek money damages *in this suit*, *i.e.*, it did not counterclaim for infringement. Again, Medtronic is simply railing against the terms of its license, which it sought so that it could challenge liability without risking breaching its license.

Medtronic also asserts (at 14) that "the only difference between this case and a traditional infringement suit is that the parties have, through their license agreement, already fixed the measure of damages to be paid in the event of an adjudication of infringement. (footnote omitted)" However, in a traditional infringement suit, the patentee seeks an injunction and past damages. In contrast, in this suit, the terms of the license preclude MFV from seeking an injunction and past damages because Medtronic's filing of a DJ action is in accordance with, and not a breach of, the 1991 license.

Medtronic asserts (at 15) that "[n]or was the Federal Circuit correct that the controversy over infringement 'had already been resolved by the license'" because, according to Medtronic, the license was entered into in 1991, and the patent claims were not issued until 2003 and 2007. However, Medtronic does not dispute that the license agreement covered subsequently issued patents. The Federal Circuit was simply referring to the fact that MFV could not assert infringement against Medtronic under the 1991 license because Medtronic had the right under the license to challenge liability.

Medtronic asserts (at 15) that "the matter in controversy is whether the patentee is entitled to take the licensee's money as compensation for infringement." However, MFV did not, and could not, counterclaim for infringement. Again, Medtronic is simply railing against the terms of the 1991 license, which it sought so that it could challenge liability without breaching the license.

Medtronic asserts (at 15, n.5) that "[c]ontrary to the Federal Circuit's suggestion, nothing in the license 'foreclosed' MFV from counterclaiming for infringement. App. 14a." However, this was not a "suggestion" by the Federal Circuit, it was a specific holding, and Medtronic does not disagree that the 1991 license permitted Medtronic to challenge liability without risking its status as a licensee and that Medtronic could not be an infringer because it was a licensee.

Medtronic also asserts (at 15) that the Federal Circuit presumed that Medtronic's products at issue were covered by the license. However, the Federal Circuit made no such presumption. Rather, the Federal Circuit merely held that Medtronic, as the only party seeking relief had the burden to prove its entitlement to such relief.

Medtronic asserts (at 17) that the Federal Circuit's decision "sharply undercut[s] the value of this Court's holding in *MedImmune*." However, the Federal Circuit's decision does not undercut *MedImmune* in any way. *MedImmune* holds that a licensee need not breach its license ("bet the farm") in order to create a justiciable controversy as to its liability under the license. Medtronic already had the right to file a DJ action against MFV without breaching the 1991 license, some 16 years before *MedImmune*. Further, the Federal Circuit's decision pertains only to "the limited circumstance" (App. 14a) of the 1991 license. Also, *MedImmune* did not consider or decide who would bear the burden of proof on claim coverage if the patentee did not counterclaim for infringement or seek any other relief.

II. Contrary to Medtronic's Assertion, the Federal Circuit's Decision Has No Far-Reaching or Negative Effect.

Medtronic asserts (at 18) that the Federal Circuit's decision will "fundamentally change the law governing relationships among licensees and licensors" because it supposedly "creates a legal presumption of infringement" "by placing the burden on a licensee to prove a negative the absence of infringement." Medtronic further asserts that this burden is "particularly difficult in a patent infringement case." Medtronic's assertion makes no sense whatsoever.

Infringement (or non-infringement) is proved by the presence (or absence) of claimed elements. The claim elements are construed by the court if the parties cannot agree to their meaning. The accused product or method is known, and can be observed and understood. Contrary to Medtronic's assertion, there is no general rule or understanding that non-infringement is always difficult to prove because non-infringement is the negative of infringement. In fact, just the opposite is true as is apparent from the many motions for summary judgment of non-infringement considered by the Federal Circuit each year.

Further, the fact of the matter is that in many cases, non-infringement may be easier to prove than infringement because unlike the case where the patentee has to prove the presence of *all* claim elements in the device at issue, the accused infringer only need show that any *one* of the claimed elements (and any equivalent) is absent to prove non-infringement.[5]

Medtronic is also wrong in asserting (at 18) that the Federal Circuit's decision creates "a legal presumption of infringement." The Federal Circuit only held that, under the terms of the 1991 license, Medtronic had the burden of proof, not that Medtronic had this burden because infringement was presumed.

Medtronic also asserts (at 18) that "[p]atents typically contain dozens, often hundreds of individual claims, infringement of any one of which triggers liability." Medtronic also asserts (at 3) that in this case "the asserted patents include hundreds of individual claims." However, Medtronic acknowledges (at 6) that in this case, only 29 claims were involved (from two patents), not hundreds of claims as implied by Medtronic (at 3, 5 and 18).

Medtronic asserts (at 19) with reference to the doctrine of equivalents ("DOE") that "[r]equiring a licensee to prove noninfringement would require it to anticipate and refute all theories under which the accused products could [be] said to perform in 'substantially the same way' as the claimed invention." Medtronic's assertion is baseless. The licensee need only address DOE for any claim limitation(s) it is asserting is not present in the device(s) at issue.

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[5] This is the familiar "all elements rule" used to prove the presence or absence of infringement.

Further with respect to DOE, Medtronic states (at 8) that the district court held that MFV "fail[ed] to execute a proper doctrine of equivalents analysis." However, the district court erred in this regard because it did not appear to recognize that such an analysis is not restricted to the "function-way-result" test, but instead, can employ the "insubstantial differences" test which Dr. Berger used in his analysis.[6]

Medtronic also asserts (at 19-20) that the Federal Circuit's decision will "increase the frequency of patent litigation, because it undermines the utility of several means by which parties have heretofore avoided disputes over products not yet in existence" and "will be particularly problematic in situations where industry participants pool their collective resources in a standards-setting organization ... ." However, Medtronic offers no reason why the Federal Circuit's decision will have any such effect and, indeed, there will be no such effect. As the Federal Circuit specifically held, its ruling applies only to "the limited circumstance" of the 1991 license. App. 14a.

Medtronic asserts (at 20) that "[u]nder *MedImmune*, licensees faced with this type of dispute should be able to file declaratory judgment actions in order to force the patentee to prove its assertion of infringement (and of essentiality)." However, *MedImmune* did not hold that in a DJ action by a licensee, that the patentee has the burden of proof on claim coverage. Rather, *MedImmune* held that there was a justiciable controversy even if the licensee continued to pay royalties to the patentee to avoid breaching the license. *MedImmune* did not hold that the patentee has the burden of proof where it does not counterclaim for infringement and the only party requesting relief is the licensee.

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[6] See MFV's opening (blue) brief before the Federal Circuit (filed July 13, 2011) at 55-60.

Similarly, Medtronic asserts (at 21) that "[a] party accused of infringing a patent falling within the scope of such a cross-license could, under *MedImmune*, file a declaratory judgment action and force the patentee to prove its infringement allegations." However, as noted above, *MedImmune* did not hold that the patentee has the burden of proof where it does not counterclaim for infringement and the only party requesting relief is the licensee.

Medtronic also asserts (at 21) that "[t]he Federal Circuit's new regime, however, will require the cross-licensee to prove that it is not an infringer, thereby decreasing incentives for parties to resolve actual and prospective disputes via broad cross-licenses to each other's patent portfolios." However, there is no "new regime." The Federal Circuit merely ruled as to the terms of the 1991 license. Parties are free to agree in any "broad cross-licenses to each other's patent portfolios" who will have any burden of proof. Medtronic had the burden of proof under the terms of the 1991 license because MFV did not, and could not, counterclaim for infringement, and Medtronic was the only party seeking relief.

Medtronic asserts (at 21-22) that "[t]he Federal Circuit's decision in this case improperly encumbers the protection afforded by *MedImmune*, by requiring the licensee to assume the burden of proof on the issue of infringement as a price of filing a declaratory judgment action." However, as noted above, *MedImmune* did not hold that the patentee has the burden of proof where it does not counterclaim for infringement and the only party requesting relief is the licensee.

Medtronic asserts (at 22) that "[t]he Federal Circuit also unnecessarily imposed a cost on licensees who attempt, in good faith, to develop products that are *not* covered by a licensed patent; such products would nonetheless be *presumed* to infringe simply upon the patentee's assertion." (Emphasis by Medtronic.) However, the Federal Circuit's decision creates no presumption of infringement. The Federal Circuit merely held that, under "the limited circumstance" (App. 14a) of the 1991 license, Medtronic had the burden of proof because MFV was precluded from counterclaiming for infringement, and Medtronic was the only party seeking relief.

Medtronic also asserts (at 22) that "[t]he Federal Circuit's ruling also rewards licensors who make out-of-court demands for royalties based on general assertions that the licensee's products infringe any of the licensed patents, knowing that the licensor has no requirement actually to prove those infringement allegations." Medtronic's assertion is baseless. If Medtronic is able to prove a *prima facie* case of non-infringement, MFV will have to disprove Medtronic's *prima facie* case, even through Medtronic will have to bear the ultimate burden of proof because it is the only party requesting relief.

Lastly, Medtronic asserts (at 22) that there is a supposed "settled principle that the patentee always bears the burden of proving its infringement allegations." However, there is no such settled principle, and Medtronic is unable to cite any case for such a principle. Rather, as held by the Federal Circuit,

> As noted, neither party here seeks money damages or an injunction based on patent infringement, which are the sorts of relief generally sought when a party seeks relief for patent infringement. *Instead, the one claim for relief sought in this case is the claim Medtronic asserts to be relieved from liability under the license by having a court declare the products in question to be noninfringing. Medtronic is the party seeking this relief and Medtronic must bear the burden of proving it is entitled to such relief.*

App. 14a (emphasis added).

CONCLUSION

For the foregoing reasons, Medtronic's petition should be denied.

Respectfully submitted,

ARTHUR I. NEUSTADT
Counsel of Record
THOMAS J. FISHER
JOHN F. PRESPER
OBLON, SPIVAK, MCCLELLAND,
MAIER & NEUSTADT, LLP
1940 Duke Street
Alexandria, VA 22314
(703) 413-3000

SIDNEY J. SILVER
SILVER, FREEDMAN &
TAFF, LLP
3299 K Street, N.W.
Washington, D.C. 20007
(202) 295-4500

April 5, 2013

Counsel for Respondent
Mirowski Family Ventures, LLC

REPLY
BRIEF

RECORD
AND
BRIEFS

Supreme Court, U.S.
FILED
APR 25 2013
OFFICE OF THE CLERK

No. 12-1128

IN THE
Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, AND MIROWSKI FAMILY VENTURES, LLC,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

Mark C. Fleming
Wilmer Cutler Pickering
Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Martin R. Lueck
Counsel of Record
Jan M. Conlin
Stacie E. Oberts
Robins, Kaplan, Miller &
Ciresi LLP
2800 LaSalle Plaza
800 LaSalle Ave.
Minneapolis, MN 55402
(612) 349-8500
mrlueck@rkmc.com

Attorneys for Petitioner

April 2013

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INTRODUCTION

In its petition, Medtronic, Inc. ("Medtronic") demonstrated that the Federal Circuit's imposition on a patent licensee of the burden to prove that its products did *not* infringe was contrary to this Court's jurisprudence and settled principles of federal civil procedure. Unless reversed, the Federal Circuit's rule will force licensees to choose between shouldering the burden of proof and breaching the license to draw a coercive infringement suit from the patentee—the very step that the Court sought to make unnecessary in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

Respondent Mirowski Family Ventures, LLC ("MFV") does not meaningfully disagree. MFV does not even cite most of the cases on which Medtronic relied, much less try to reconcile the Federal Circuit's reasoning with them. Nor does it deny that, under the Federal Circuit's holding, the only way Medtronic could have demanded that MFV prove its accusation that Medtronic's products infringed MFV's patents was by breaching the license such that MFV would sue.

MFV's efforts to defend the Federal Circuit's rule are misguided and, in any event, are arguments this Court should consider on the merits, not reasons to deny review in the first place. The petition should be granted.

ARGUMENT

1. MFV's primary contention is that the decision below is somehow limited to the specific 1991 license between these parties—an argument

MFV makes at least four times by selectively quoting the Federal Circuit's statement that its holding applied only in a "'limited circumstance.'" Opp. 13, 20, 23, 25. But the Federal Circuit's full holding, when not truncated, decrees a rule that applies to *any* action for a declaratory judgment of noninfringement under *MedImmune*:

> "Therefore, this court holds that in the limited circumstance *when an infringement counterclaim by a patentee is foreclosed by the continued existence of a license, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license* bears the burden of persuasion."

Pet. App. 14a (emphasis added). That holding is not limited to the 1991 license between Medtronic and MFV. Rather, it applies to any declaratory judgment action involving a patent license agreement in the "post-*MedImmune* world" (Pet. App. 9a), namely when a patent licensee seeks a declaration that "the agreement does not call for royalties because [its] product does not infringe the patent." *MedImmune*, 549 U.S. at 135. The Federal Circuit's description of that situation as a "limited circumstance" only underscores that it has allocated the burden of proof in *MedImmune*-type declaratory judgment cases *differently* from how it is allocated in other federal litigation (and certainly in other *patent infringement* litigation). That divergence is a reason to grant review, not to deny it.

MFV's assertion that "Medtronic had the burden of proof under the terms of the 1991 license"

(Opp. 24)[1] is likewise plainly incorrect. Nothing in the license purports to dictate the burden of proof; it provides only that Medtronic may file a declaratory judgment action seeking adjudication of MFV's assertions of infringement. Pet. App. 24a. It was the *Federal Circuit* that imposed the burden of proof on Medtronic simply because it was a declaratory judgment plaintiff in a *MedImmune* case. Pet. App. 14a.

2. MFV also asserts (Opp. 20, 23, 24, 25) that *MedImmune* did not itself address the burden of proof. Medtronic never suggested otherwise. But this Court *did* say that a licensee who seeks a federal court's assessment of a patentee's demand for royalties should not be required to repudiate the license and invite the patentee to sue for infringement, thereby "risk[ing] such serious consequences" as treble damages and attorney's fees. *MedImmune*, 549 U.S. at 122; *see id.* at 137 ("We hold that [licensee] was not required ... to break or terminate its 1997 license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed.").

The Federal Circuit's decision in this case places a hefty price tag on a *MedImmune*-type declaratory judgment action, by forcing the patentee to shoulder the burden of proving noninfringement, contrary to the undisputed standard rule in patent litigation. *See Imhauser v. Buerk*, 101 U.S. 647, 662 (1880) ("[T]he burden to prove infringement never shifts."); *see also R.R. Co. v. Mellon*, 104 U.S. 112,

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[1] *See also* Opp. 18 (asserting that Medtronic disputes "the terms of the license"); *id.* 19 ("Medtronic is simply railing against the terms of the 1991 license[.]").

119 (1881). Put another way, a licensee who wishes to require a *patentee* to prove its infringement assertions must now "bet the farm" or "risk treble damages and the loss of ... its business before seeking a declaration of its actively contested legal rights." *MedImmune*, 549 U.S. at 134.[2]

MFV does not meaningfully disagree with any of this. Instead, it simply claims that the Federal Circuit's rule creates an acceptable state of affairs. But that is the question this Court should decide on the merits; again, it is not a reason to deny review.

3. MFV claims that this case differs from infringement cases in which the patentee must prove infringement because MFV did not and could not file a counterclaim. Opp. 17, 18, 19, 20, 24, 25. But that is simply a repetition of the court of appeals' holding; it is not an argument for its correctness, much less an argument against this Court's review. MFV does not explain *why* the absence of a counterclaim should justify shifting the burden of proof—particularly in the face of this Court's teachings that "the burden to prove infringement never shifts" (*Imhauser*, 101 U.S. at 621); that the burden of proof is "a 'substantive'

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[2] MFV's argument that Medtronic bore no such risks in *this case* (Opp. 18) again misses the point. Under the Federal Circuit's rule, Medtronic's choice to file a declaratory judgment action under *MedImmune* (and thus avoid breaching the license) forced it to assume the burden of proving non-infringement. Unless this Court grants the petition and reverses the judgment below, the only way for Medtronic to ensure that MFV is required to prove its assertion that Medtronic's implantable cardiac stimulation devices infringe would be to breach the license such that MFV filed a coercive infringement claim, which would expose Medtronic to the risks of treble damages, attorney's fees, a permanent injunction, and a finding that it repudiated the license even as to *other* licensed products.

aspect of a claim" (*Raleigh v. Illinois Dep't of Revenue*, 530 U.S. 15, 20-21 (2000)); and that the declaratory nature of an action does not alter such substantive features (*Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 508-509 (1959)). This Court has never recognized an exception to these principles that turns on the presence or absence of a counterclaim.[3]

MFV states that "a patentee need prove infringement only when it asserts it." Opp. 15. But MFV most certainly "assert[ed]" infringement—indeed, it was MFV's letters to Medtronic accusing seven Medtronic devices of infringing 29 claims of the two patents-in-suit that made Medtronic's declaratory judgment action necessary. Pet. App. 4a, 24a. In substance, the present case does not meaningfully differ from declaratory-judgment actions in which there *is* a formal counterclaim of infringement. The only difference is that the parties have already determined—and Medtronic is already paying out—the amount of damages MFV would receive if its infringement contention prevailed. *See* Pet. 14.

4. MFV insists (Opp. 20, 22, 25) that the Federal Circuit did not presume that Medtronic's products infringe. But the Federal Circuit explicitly held that Medtronic must bear both the initial burden of production and the ultimate risk of

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[3] MFV curiously contends that Medtronic "is unable to cite any case" demonstrating that the patentee always bears the burden of proving its infringement allegations. Opp. 26. Medtronic cited several such cases, including the Federal Circuit's own recognition of that rule. *See* Pet. 10-12 (citing *Mellon*, *Imhaeuser*, and *Cammeyer v. Newton*, 94 U.S. 225, 231 (1877)); Pet. App. 10a-11a (citing cases).

nonpersuasion. Pet. App. 13a ("Medtronic must present evidence showing that it is entitled to [] relief. If neither party introduced any evidence regarding infringement or noninfringement there is no principled reason why Medtronic should receive the declaration of noninfringement it seeks."); *see also id.* 9a-10a (citing case law and treatises stating that the party bearing the burden of proof is also expected to bear the risk of failure of proof or persuasion).

The Federal Circuit's requirement that the licensee bear the burden of production is the hallmark of a "presumption." *See* Fed. R. Evid. 301 ("[T]he party against whom a presumption is directed has the burden of producing evidence to rebut the presumption."). Moreover, the Federal Circuit's requirement that the licensee bear the risk of nonpersuasion in *MedImmune*-type actions means that the licensee will suffer an infringement ruling if its evidence fails to convince the trier of fact. *Cf. Director, Office of Workers' Comp. Progs. v. Greenwich Collieries*, 512 U.S. 267, 282 (1994) (Souter, J., dissenting) (equating "burden of proof" with "the risk of nonpersuasion"). Regardless of whether this is called a "presumption," a "risk of nonpersuasion," or something else, the court of appeals' new rule conflicts with the well-established rule (correctly applied by the district court, Pet. App. 40a-41a) that a patentee bears the burden of proving infringement, even in a declaratory judgment action. *Cf. Mellon*, 104 U.S. at 119.

MFV does not even address, much less dispute, Medtronic's discussion of declaratory judgment cases of other courts of appeals. Pet. 16-17. Although the Federal Circuit invoked analogies to insurance law and cited decisions it believed to be "consistent" with its reasoning (Pet. App. 13a-14a), the courts of appeals are at best divided on this question in the insurance context. *See, e.g.*, *American Eagle Ins. Co. v. Thompson*, 85 F.3d 327, 331 (8th Cir. 1996) (placing burden of proof on declaratory judgment defendant because he "asserted the affirmative of the question asked of the jury and ... would lose in the absence of any evidence on the issue"). MFV does not attempt to defend the Federal Circuit's reliance on a handful of insurance cases that, on their own, reflect a division in the circuits.

5. MFV similarly offers no real response to the far-reaching negative effects that are likely to arise under the Federal Circuit's misallocation of the burden of proof. *See* Pet. 18-22. MFV primarily repeats its incorrect assertions that the Federal Circuit's rule was somehow limited to these parties' 1991 license—which it clearly was not—and that the court did not impose any presumption of infringement, which it plainly did. *See supra* pp. 1-3, 5-6.

MFV ventures that requiring a licensee to offer affirmative evidence of a negative proposition is ultimately not problematic, because "the licensee need only address [the doctrine of equivalents] for any claim limitation(s) it is asserting is not present in the device(s) at issue." Opp. 22. MFV misses the mark entirely. As Medtronic explained, the difficulty in anticipating and refuting any possible theory of equivalence remains even as to *one* claim element, because a patentee may argue equivalence based on numerous theories that are not evident on the face of the patent—or, as in this case, are not evident even from the patentee's own expert testimony. *See* Pet.

19. And once again, MFV's assertion regarding the relative difficulty with which the licensee could carry the burden of proof is an argument this Court may and should evaluate on the merits. It is not a reason to deny review of a question the Federal Circuit has decided in a manner contrary to several precedents of this Court, to comparable declaratory judgment decisions in other circuits, and to the reasoning that animated *MedImmune*.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

Mark C. Fleming
Wilmer Cutler Pickering
Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Martin R. Lueck
Counsel of Record
Jan M. Conlin
Stacie E. Oberts
Robins, Kaplan, Miller &
Ciresi LLP
2800 LaSalle Plaza
800 LaSalle Ave.
Minneapolis, MN 55402
(612) 349-8500
mrlueck@rkmc.com

Attorneys for Petitioner

April 2013

JOINT
APPENDIX

No. 12-1128

Supreme Court, U.S.
FILED
JUL 26 2013
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

MEDTRONIC INC.,

Petitioner,

v.

BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, AND MIROWSKI FAMILY VENTURES, LLC,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

JOINT APPENDIX

ARTHUR I. NEUSTADT
Counsel of Record
THOMAS J. FISHER
OBLON, SPIVAK,
MCCLELLAND, MAIER
& NEUSTADT LLP
1940 Duke Street
Alexandria, VA 22314
(703) 413-3000
aneustadt@oblon.com

SIDNEY J. SILVER
SILVER, FREEDMAN
& TAFF LLP
3299 K Street, NW
Washington, DC 20007

Counsel for Respondent Mirowski Family Ventures, LLC

MARTIN R. LUECK
Counsel of Record
JAN M. CONLIN
STACIE E. OBERTS
ROBINS KAPLAN MILLER
& CIRESI LLP
2800 Lasalle Plaza
800 Lasalle Avenue
Minneapolis, MN 55402
(612) 349-8500
mrlueck@rkmc.com

SETH P. WAXMAN
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006

Counsel for Petitioner

ADDITIONAL COUNSEL LISTED ON INSIDE COVER

PETITION FOR CERTIORARI FILED MARCH 14, 2013
CERTIORARI GRANTED MAY 20, 2013

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U.S. DISTRICT COURT
DISTRICT OF DELAWARE (WILMINGTON)
CIVIL DOCKET FOR CASE #: 1:07-CV-00823-SLR

Medtronic Inc. v. Boston Scientific Corporation et al
Assigned to: Judge Sue L. Robinson

Date Filed	#	Docket Text
12/17/2007	1	COMPLAINT filed with Jury Demand against Boston Scientific Corporation, Guidant Coropration, Mirowski Family Ventures L.L.C.—* * * filed by Medtronic Inc. * * *
		* * *
02/10/2009	108	SECOND AMENDED COMPLAINT against all defendants—filed by Medtronic Inc. * * *
		* * *
02/25/2009	114	ANSWER to Amended Complaint ANSWER to 108 Amended Complaint * * *, COUNTERCLAIM against Medtronic Inc. by Mirowski Family Ventures L.L.C. * * *
02/25/2009	115	ANSWER to Amended Complaint ANSWER to 108 Amended Complaint * * * by Boston Scientific Corporation, Guidant Coropration. * * *
		* * *
01/04/2010	177	Proposed Pretrial Order by Boston Scientific Corporation, Guidant Coropration, Medtronic Inc., Mirowski Family Ventures L.L.C. * * *

* * *

01/07/2010		SO ORDERED, by Judge Sue L. Robinson on 1/7/2010 re 177 Proposed Pretrial Order filed by Boston Scientific Corporation, Guidant Coropration, Medtronic Inc., Mirowski Family Ventures L.L.C. * * *
		* * *
01/25/2010		Minute Entry for proceedings held before Judge Sue L. Robinson—Bench Trial held on 1/25/2010 (DAY 1). * * *
01/26/2010		Minute Entry for proceedings held before Judge Sue L. Robinson—Bench Trial held on 1/26/2010 (DAY 2). * * *
01/27/2010		Minute Entry for proceedings held before Judge Sue L. Robinson—Bench Trial held on 1/27/2010 (DAY 3). * * *
01/28/2010		Minute Entry for proceedings held before Judge Sue L. Robinson—Bench Trial completed on 1/28/2010 (DAY 4). * * *
		* * *
03/13/2010		Minute Entry for proceedings held before Judge Sue L. Robinson—Bench Trial completed on 3/13/2010. * * *
		* * *
03/30/2011	256	OPINION. Signed by Judge Sue L. Robinson on 3/30/2011. * * *

03/30/2011	257	ORDER re 256 Opinion. Signed by Judge Sue L. Robinson on 3/30/2011. * * *
03/30/2011	258	JUDGMENT in favor of plaintiff Medtronic, Inc. and against defendants Boston Scientific Corporation, Guidant Corporation, and Mirowksi Family Ventures L.L.C. as to noninfringement of Reissued U.S. Patents Nos. RE 38,119 and RE 39,897. IT IS FURTHER ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of defendants Boston Scientific Corporation, Guidant Corporation, and Mirowski Family Ventures L.L.C. and against plaintiff Medtronic, Inc. as to validity and enforceability of Reissued Patents Nos. RE 38,119 and RE 39,897. (CASE CLOSED) Signed by Judge Sue L. Robinson on 3/30/2011. * * *

* * *

04/01/2011	260	NOTICE OF APPEAL to the Federal Circuit of 256 Opinion, 257 Order, 258 Judgment,,. Appeal filed by Mirowski Family Ventures L.L.C. * * *

* * *

04/12/2011	263	RULE 54(b) CERTIFICATION. Signed by Judge Sue L. Robinson on 4/12/2011. * * *

* * *

04/27/2011	265	NOTICE OF CROSS APPEAL to the Federal Circuit of 256 Opinion, 257 Order, 258 Judgment,,. Cross Appeal filed by Medtronic Inc. * * *
		* * *
04/28/2011	266	Supplemental NOTICE OF APPEAL to the Federal Circuit of 256 Opinion, 257 Order, 258 Judgment,,. Appeal filed by Mirowski Family Ventures L.L.C. * * *
		* * *
05/18/2011	268	STIPULATION of Dismissal by Mirowski Family Ventures L.L.C. * * *

* * *

U.S. COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
MEDTRONIC V. BOSTON SCIENTIFIC
2011-1313

* * *

Date	History
	* * *
9/18/2012	Disposition: Vacated and Remanded ; by Panel
12/20/2012	Mandated on

* * *

>> Entries for Case Number: 2011-1313 <<

* * *

Entry 40 : Entered : 3/6/2012, Submitted after ORAL ARGUMENT by Arthur I. Neustadt and Martin R. Lueck. Panel: Lourie, Linn and Prost.

* * *

REHEARINGS

* * *

10/17/2012 Entry 42 : Appellant [Mirowski Family Ventures, LLC]—Combined Petition for Panel Rehearing and Rehearing En Banc. * * *

Response requested from: Cross-Appellant (Medtronic Inc.). Response due: 11/8/2012. Response filed: 11/8/2012

Entry 45: Petition/En Banc Action: Denied/Denied on 12/14/2012.

10/17/2012 Entry 43 : Cross-Appellant [Medtronic Inc.]—Combined Petition for Panel Rehearing and Rehearing En Banc. * * *

Response requested from: Appellant (Mirowski Family Ventures, LLC). Response due: 11/8/2012. Response filed: 11/8/2012

Entry 44: Petition/En Banc Action: Denied/Denied on 12/14/2012.

* * *

LICENSE AGREEMENT

THIS AGREEMENT is made this 13th day of May, 1991, by and among Eli Lilly and Company and its Affiliates (hereinafter collectively defined as "Lilly"), an Indiana corporation having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285; Cardiac Pacemakers, Inc. and its Affiliates (hereinafter collectively defined as "CPI"), a Minnesota corporation having its principal place of business at 4100 Hamline Avenue North, St. Paul, Minnesota 55112-5798 and a wholly owned subsidiary of Lilly; and Medtronic, Inc. and its Affiliates (hereinafter collectively defined as "Medtronic"), a Minnesota corporation having its principal place of business at 7000 Central Avenue N.E., Minneapolis, MN 55432.

RECITALS

* * *

B. CPI, Medtronic and certain Affiliates of Lilly, CPI and Medtronic are engaged in, inter alia, the design and development of Cardiac Stimulation Devices;

C. Various aspects of such Cardiac Stimulation Devices have been patented by CPI, Medtronic and certain Affiliates of Lilly and the parties have acquired license rights which they may sublicense.

D. At the present time Lilly, CPI and Medtronic are adverse parties in Litigation in which a number of claims and counterclaims have been raised.

E. Lilly, CPI and Medtronic desire to settle all Litigation upon the terms and conditions set forth in this Agreement and the contemporaneously executed Settlement Agreement and Purchase Agreement, all of which comprise one agreement and are referred to as "The Agreement".

The parties agree as follows:

ARTICLE I

Definitions of Terms

For the purposes of The Agreement, the following terms shall have the meaning specified below. All capitalized terms used and not otherwise defined herein shall mean as defined in the Settlement Agreement or Purchase Agreement, as the case may be.

* * *

Section 1.02. Cardiac Stimulation Devices. "Cardiac Stimulation Devices" means devices for electrically stimulating or shocking the heart which are suitable for use by or with human patients. The term "Cardiac Stimulation Devices" includes, without limitation; cardiac pacemakers, antitachycardia pacemakers, cardioverters and defibrillators, including combinations thereof, whether implantable or not; pulse generators and other waveform generators for such devices; leads, electrodes, sensors and fixation mechanisms for coupling such generators in a stimulating, shocking or sensing relationship to the heart; and data dispensing, processing and gathering systems for such devices including programmers, pacing system analyzers, defibrillation system analyzers, testers, encoders, decoders, transmitters, receivers, and computer software-controlled systems, including the software. The term "Cardiac Stimulation Devices" excludes, by way of example and not limitation, skeletal muscle stimulators, nerve stimulators, bone growth stimulators, drug release pumps, cardiac assist systems and pumps, artificial hearts, power sources, catheter ablation devices, and mapping devices.

Section 1.03. Effective Date. "Effective Date" means May 13, 1991.

Section 1.04. Field of Use. "Field of Use" means the use of Cardiac Stimulation Devices in the field of cardiac rhythm management but excluding external defibrillators employing only skin electrodes for defibrillation such as those sold by Physio Control Corp. under the Lifepack trade name.

Section 1.05. Licensed Patents. "Licensed Patents" means any and all patents relating to Cardiac Stimulation Devices in the Field of Use owned by Lilly, CPI or Medtronic; or licensed to Lilly, CPI or Medtronic under which Lilly, CPI or Medtronic have a right to grant sublicenses which are:

a. issued in any country on or before the Effective Date; or

b. issued after the Effective Date, but which patent is a counterpart in any country of a patent described in subparagraph (a) hereof, regardless of whether such patent matures from a continuation, continuation-in-part, division, reissue, or reexamination of such patent described in subparagraph (a) hereof and regardless of whether such patent matures from a convention or non-convention case; or any other substitution, renewal, extension, addition, utility model, or other patent, foreign or U.S.

c. issued after the Effective Date from patent applications filed on or before the Effective Date, including all patents maturing from continuations, continuations in part, and divisional applications or reissues or reexaminations of such patents, and further including all patents which are counterparts of the patents described in this subparagraph (c), regardless of whether such patent matures from a convention or non-convention case; or any other substitution, renewal, extension, addition, utility model, or other patent, foreign or U.S.

Without limitation of the foregoing, the term "Licensed Patent" specifically includes all patents and patent applications listed on Exhibit A of this Agreement. The parties believe that Exhibit A is complete as of the Effective Date and any omissions from Exhibit A will be deemed to be inadvertent.

ARTICLE II

Cross License

Section 2.01. License. Subject to the terms, conditions and limitations set forth herein, (a) Lilly and CPI grant to Medtronic a non-exclusive, fully paid up (except as provided for herein) worldwide license or sublicense, as the case may be, without the right to sublicense under any license or sublicense, under all Licensed Patents of Lilly and CPI to make, have made, use, sell and have sold Cardiac Stimulation Devices in the Field of Use; to supply or cause to be supplied components of Cardiac Stimulation Devices which are used in the Field of Use; and to import into any jurisdiction where Licensed Patents of Lilly and CPI are effective, Cardiac Stimulation Devices for use in the Field of Use or components of Cardiac Stimulation Devices for use in the Field of Use which are manufactured in accord with a method of any Licensed Patent of Lilly and/or CPI; and (b) Medtronic grants to Lilly and CPI, a non-exclusive, fully paid up (except as provided for herein) worldwide license or sublicense, as the case may be, without the right to sublicense under any license or sublicense, under all Licensed Patents of Medtronic to make, have made, use, sell and have sold Cardiac Stimulation Devices in the Field of Use; to supply or cause to be supplied components of Cardiac Stimulation Devices which are used in the Field of Use; and to import into any jurisdiction where Licensed Patents of Medtronic are effective, Cardiac Stimulation Devices for use in the Field of Use or components of Cardiac Stimulation Devices for use in the Field of Use which are manufactured in accord with a method of any Licensed Patent of Medtronic. If any party has Cardiac Stimulation Devices made for it under the above license grant, such Cardiac Stimulation Devices must bear the tradename of that party, and must be sold under a trademark of that party by that party's sales force or established distributor network. Any royalty bearing license agreement under Licensed Patents for Cardiac Stimulation Devices in the Field of Use in existence between the parties prior to the Effective Date shall remain in existence in its entirety and shall remain royalty bearing in accordance with its terms except that the royalty rate shall be one-half of that specified in such license agreement. Any Licensed Patent of, respectively, Lilly, CPI or Medtronic under which Lilly, CPI or Medtronic is paying a running royalty or other payment based on usage to the inventor or prior owner will be licensed hereunder at that running royalty or other payment rate based on usage. It is the parties intention, under the previous sentence, that only current payments based on usage be made to the other party, and that no "front end" payments be recoverable thereunder. Whenever the combined paid royalties of the licensee and all sublicensees reaches the royalty cap under any license, no further royalties shall be due from the sublicensee. Minimum payments shall be the sole responsibility of the licensee. Any royalties from a sublicensee which a licensee is permitted to retain shall be promptly rebated to the sublicensee.

* * *

ARTICLE III

Third Party Sublicense

Each party may elect to be sublicensed under existing third party patents licensed to any other party where such sublicensing is permitted under the terms of such license. Such election shall occur by notice of the electing party to the other party. Such sublicenses are accepted subject to all disclosed terms and conditions, including royalties and royalty caps, in existence between the party and the third party licensor as of the Effective Date. To the extent more favorable terms for any such third party license are negotiated by a party, after the Effective Date, any sublicense to a party shall include the more favorable terms. For purposes of this Article III and Section 2.02(d), intercompany royalties payable between Affiliates shall not be considered. In the event that sublicensing under such existing third party licenses is prohibited, the licensed party will make a good faith effort, at the option of the other parties, to procure the right to sublicense the other parties, at no cost to the licensed party. (Medtronic shall have no obligation to procure from Telectronics Holdings Ltd., Telectronics Pty. Ltd., Medical Telectronics Holdings & Finance Co. (BV) or Telectronics NV a sublicense on behalf of Lilly or CPI.) The intention of the parties under this Article is that no party shall be competitively disadvantaged in the marketplace because of these third party licenses and the parties will cooperate to achieve this goal.

* * *

With respect to the Mirowski license and any new Medtronic devices, if Medtronic is not paying royalties on such new device, and Lilly or the Mirowski family believes that such device infringes one or more of the Mirowski patent(s), Lilly shall notify Medtronic of such infringement. Medtronic shall have ninety days to cure the nonpayment of royalties. If Medtronic fails to pay such royalties within the cure period and continue payment thereunder Lilly shall have the right to terminate the sublicense as to that Mirowski Patent(s).

If Medtronic pays the royalty, Medtronic shall, while maintaining its sublicense under the License Agreement, have the right to challenge the validity and enforceability of any patent under the Mirowski license, other than U.S. Patents Nos. 3,942,536; 4,223,678; 4,316,472; 4,407,288 and 4,572,191 and shall have the right to challenge Lilly's assertion of infringement of any of the Mirowski patents through a Declaratory Judgment action. In such action, Lilly and the Mirowski family shall not make claims for wilful infringement or punitive damages and neither Lilly nor the Mirowski family shall seek injunctive relief. In any such litigation, the losing party shall pay all reasonable attorneys' fees and court costs for the winning party and, if Medtronic is the winning party, all royalties paid from the date Medtronic files suit shall immediately be refunded to Medtronic including simple interest at a rate of nine and one-half percent (9.5%) per annum. In any such litigation if Medtronic is found not to have any royalty obligations with respect to the products in dispute then it shall be considered the winning party.

Lilly represents that it has and will continue to have the obligation to the Mirowski family under the Mirowski license to enforce the Mirowski patents. Lilly recognizes that Medtronic should not be competitively disadvantaged by the Mirowski license; therefore if a third party whose products compete with Medtronic's products is, in Medtronic's opinion, infringing any of such patents, Medtronic can notify Lilly, in writing, of such infringement and the patents must be enforced or Lilly shall give Medtronic its reasons for not enforcing such patent(s). Any controversy between Lilly and Medtronic over whether such patent(s) should be enforced and whether Lilly has good reasons for not enforcing such patent(s) may be submitted to ADR at the request of either party. Lilly shall not be required to conduct more than two (2) such enforcement actions at any time.

* * *

ARTICLE IX
General Provisions

* * *

Section 9.05. Governing Law. All matters affecting the interpretation, form, validity and performance of The Agreement shall be decided under the laws of the state of Minnesota, including its procedural laws; provided, however, that nothing in Minnesota procedural law shall be deemed to alter or affect the applicability of the Federal Arbitration Act as governing arbitration of disputes as provided in Exhibit B and, provided further, that no Minnesota laws or rules of arbitration shall be applicable.

* * *

IN WITNESS WHEREOF, the parties hereto have caused this License Agreement to be executed and duly attested by their corporate officers duly authorized for this purpose.

ELI LILLY AND COMPANY

By: /s/ [illegible]

Title: President—MDD Division

Date: 5-13-91

ATTEST:

By: /s/ [illegible]

CARDIAC PACEMAKERS, INC.

By: /s/ [illegible]

Title: President & CEO

Date: 5/13/91

ATTEST:

By: /s/ [illegible]

MEDTRONIC, INC.

By: /s/ [illegible]

Title: President and CEO

Date: May 13, 1991

ATTEST:

By: /s/ [illegible]

EXHIBIT A

LICENSE AGREEMENT

* * *

LICENSED PATENTS SUBJECT TO THIRD PARTY ROYALTY OBLIGATIONS

Royalty Recipients	Licensed Patents	Subject Matter
	* * *	
Dr. M. Mirowski	3,942,536	Implantable defibrillation and related cardiac rhythm management therapies
	3,952,750	
	4,030,509	
	4,161,952	
	4,164,946	
	4,184,493	
	4,202,340	
	4,210,149	
	4,223,678	
	4,254,775	
	4,262,673	
	4,270,549	
	4,291,707	
	4,300,567	
	4,303,075	
	4,314,095	
	4,316,472	
	4,323,075	
	4,393,877	
	4,407,288	
	4,440,172	
	4,475,551	
	4,488,555	
	4,559,946	
	4,567,883	

4,572,191
4,592,367
4,603,705
4,614,192
4,705,043
4,765,341
4,768,512
4,797,620
4,928,688
4,969,463
U.S. Serial No. 07/638,511
D274262
D273514
D280930
Re. 27,757
Re. 27,652

* * *

EXHIBIT C

PRESS RELEASE

Cardiac Pacemakers, Inc., its parent company, Eli Lilly and Company (NYSE: LLY), and Medtronic, Inc. (NYSE: MDT) announced today that they have settled all on-going litigation among the companies.

In various litigation dating back to 1985 each company alleged infringement by the other of certain patents covering implantable pacemakers and defibrillators used in the treatment of abnormal heart rhythms.

All current litigation between the companies will be dismissed, and the parties have cross-licensed all patents covering cardiac stimulation devices that electrically manage the rhythm of the heart. The companies have also entered into an agreement under which Medtronic will supply certain bradycardia pacing products to Cardiac Pacemakers, Inc. for a defined period of time.

Medtronic, Inc. headquartered in Minneapolis, is a developer and manufacturer of biomedical devices for improving cardiovascular and neurological health. Cardiac Pacemakers, Inc. headquartered in St. Paul, develops and markets therapeutic implantable cardiac rhythm management systems. Eli Lilly and Company, headquartered in Indianapolis, is a global research-based corporation that develops, manufactures, and markets pharmaceuticals, medical instruments and diagnostic products, and agricultural products.

* * *

Execution Copy

LITIGATION TOLLING AGREEMENT

THIS AGREEMENT is among Mirowski Family Ventures, LLC, a Limited Liability Company organized and existing under the laws of the State of Maryland, Medtronic, Inc., a Minnesota corporation, and Guidant Corporation, an Indiana corporation.

WHEREAS, Mirowski owns U.S. Patent No. Re 38,119 entitled "Method and Apparatus for Treating Hemodynamic Disfunction";

WHEREAS, pursuant to an Exclusive License Agreement dated January 30, 1973, Eli Lilly and Company obtained an exclusive license under certain patents now owned by Mirowski, including the '119 Patent;

WHEREAS, Lilly granted Medtronic a sublicense under certain patents including the '119 Patent pursuant to a License Agreement dated May 13, 1991, as has been amended from time to time;

WHEREAS, Guidant is successor in interest to Lilly pursuant to the Amended and Restated Exclusive License Agreement dated January 28, 2004, between Mirowski and Guidant to which Lilly concurred;

WHEREAS, Mirowski and Guidant believe that the InSync III, InSync Marquis, and InSync III Marquis cardiac resynchronization products introduced by Medtronic are covered by the '119 Patent and, by Settlement Agreement of the Parties, dated August 28, 2003 Medtronic has been paying royalties into two escrow accounts on sales of the First Products while Medtronic is seeking in *Medtronic, Inc. v. Guidant Corp.*, No. 03-848-SLR (D. Del.), a declaration that the '119 Patent is invalid, which case remains pending;

WHEREAS, Medtronic is currently selling additional cardiac resynchronization devices including the InSync ICD, InSync II Marquis, InSync Maximo, InSync, and InSync Sentry, which Mirowski and Guidant believe are covered by the '119 Patent;

WHEREAS, Medtronic believes the '119 Patent is invalid, unenforceable and that the First Products and the Second Products do not infringe the '119 Patent and Medtronic to date has not paid royalties on the Second Products;

WHEREAS, infringement and the validity and enforceability of the '119 Patent are also at issue in a pending action between Guidant and St. Jude in *St. Jude Medical, Inc. v. Guidant Corp.*, No. 04-0067-SLR (D. Del.);

WHEREAS, Medtronic has the right in accordance with the Medtronic Agreement, to challenge allegations of infringement of the '119 patent as well as the validity and enforceability of the '119 Patent through one or more Declaratory Judgment actions, and the parties wish to toll and suspend any and all such Declaratory Judgment actions concerning Second Products and Subsequent Products until conclusion of the St. Jude Litigation or until October 1, 2007, whichever is later; and

WHEREAS, by reason of the foregoing, an actual controversy exists between and among the Parties under 35 U.S.C. § 271 as to the scope, validity and enforceability of the '119 Patent, and whether or not any valid and enforceable claims thereof cover Medtronic products, and consequently the proper distribution of substantial monies residing in or to be paid into various escrow accounts;

NOW, THEREFORE, In consideration of the mutual covenants set forth herein, the Parties agree to the foregoing recitals and to the following terms and conditions:

1. Definitions:

1.1 "Accused Cardiac Resynchronization Products" means: (i) Second Products or Subsequent Products of Medtronic that Guidant or Mirowski accuse of infringing the '119 Patent or any Subsequent Reissue Patent(s) and (ii) Medtronic's InSync III product with respect to claims 1-14 of the '119 Patent and any Subsequent Reissue Patent(s).

* * *

1.6 "DJ Suspension Period" means the later of: (a) final resolution of the St. Jude Litigation (including settlement thereof), or (b) October 1, 2007.

* * *

1.8 "Final DJ Action" means a declaratory judgment action filed by Medtronic within ninety (90) days after receiving a notice of infringement from Guidant or Mirowski after the DJ Suspension Period has expired, including all subsequent actions through the exhaustion of all appeals.

1.9 "First Products" means Medtronic's InSync III, InSync Marquis, and InSync III Marquis products.

* * *

1.14 "Medtronic Agreement" means a sublicense to certain patents owned by Mirowski, including the '119 Patent pursuant to a License Agreement dated May 13, 1991, as has been amended from time to time.

1.15 "Medtronic Litigation" means the action captioned *Medtronic, Inc. v. Guidant Corp.*, No. 03-848-SLR (D. Del.), including all subsequent actions through the exhaustion of all appeals.

1.16 "Medtronic/Mirowski Account" means an account to be established by Medtronic to hold disputed royalty payments of Medtronic for sales of Second Products and Subsequent Products after October 31, 2004 and interest thereon.

* * *

1.20 "Second Products" means Medtronic's InSync ICD, InSync II Marquis, InSync Maximo, InSync, and InSync Sentry products.

1.21 "St. Jude Litigation" means the action captioned *St. Jude Medical, Inc. v. Guidant Corp.*, No. 04-0067-SLR (D. Del.), including all subsequent actions through the exhaustion of all appeals.

1.22 "Subsequent Products" means Medtronic's implantable cardiac resynchronization devices released before or after the Effective Date of this Agreement but not including First Products or Second Products.

1.23 "Subsequent Reissue Patent(s)" means any patent claiming priority to U.S. Patent No. Re 38,119.

1.24 "The '119 Patent" means U.S. Patent No. Re 38,119 entitled "Method and Apparatus for Treating Hemodynamic Disfunction".

* * *

5. The Parties agree that any obligation to initiate any declaratory judgment action permitted or required by the Medtronic Agreement with respect to the Second Products or any Subsequent Products is tolled and suspended until the conclusion of the DJ Suspension

Period and for ninety (90) days after receipt by Medtronic of a notice of infringement from Guidant or Mirowski.

* * *

7. The Parties agree that:
   (a) Within thirty (30) days after the Effective Date of this Agreement, Medtronic will identify, in writing, each of the Subsequent Products released prior to the Effective Date of this Agreement, and provide appropriate physician or other manuals to Guidant and Mirowski (who shall retain them, if not public, as confidential) for each Subsequent Product identified; and
   (b) Within thirty (30) days after the release of each of the Subsequent Products released after the effective date of this Agreement, Medtronic will identify, in writing, the Subsequent Product(s) and provide appropriate physician or other manuals to Guidant and Mirowski (who shall retain them, if not public, as confidential) for each Subsequent Product identified; and
   (c) Within sixty (60) days after the expiration of the DJ Suspension Period, for any claim of the '119 Patent or Subsequent Reissue Patent(s) that is not adjudicated invalid or unenforceable in the St. Jude Litigation or the Medtronic Litigation, Guidant or Mirowski may notify Medtronic, in writing, identifying all Accused Cardiac Resynchronization Products (if any) and any claims in the '119 Patent or Subsequent Reissue Patent(s) (but in no event, more than thirty (30) claims in total) that Guidant or

Mirowski asserts are infringed by the Accused Cardiac Resynchronization Products; and if Guidant or Mirowski fail to provide written notice within the time period specified above with respect to any product as to which Medtronic has complied with paragraphs 7(a) and 7(b) above, any claim against any such Medtronic product not included in the Accused Cardiac Resynchronization Products shall be waived and any disputed royalties paid into the Medtronic/Mirowski Escrow on account thereof, and interest thereon, shall be released to Medtronic.

8. If Guidant or Mirowski provides timely written notice of infringement as set forth in Section 7(c) of this Agreement, Medtronic may within 90 days after such notice, initiate in the Delaware Federal Court the Final DJ Action challenging infringement, unenforceability and/or validity of the asserted claims of the '119 Patent and any asserted claims of any Subsequent Reissue Patent(s). At the time of the filing of the Final DJ Action, Medtronic will specifically identify each of the Accused Cardiac Resynchronization Products that Medtronic believes do not infringe the asserted claims of the '119 Patent or any asserted claims of any Subsequent Reissue Patent(s). For any Accused Cardiac Resynchronization Products not identified by Medtronic as non-infringing during the Final DJ Action, Medtronic will be precluded from bringing a subsequent declaratory judgment action asserting non-infringement of such product(s) notwithstanding any provisions to the contrary in the Medtronic Agreement and, accordingly, any corresponding royalties in the Medtronic/Mirowski Account, and interest thereon, shall be released to Mirowski.

9. The Final DJ Action will be conducted under the following parameters:

(a) Medtronic will be bound on a claim-by-claim basis only for: (i) enforceability, including inequitable conduct and patent misuse; (ii) invalidity under 35 U.S.C. § 101, § 102, and § 103; or (iii) each separate validity issue arising under 35 U.S.C. § 112, regardless of the claim construction adopted in the St. Jude Litigation; but only if such issues are adjudicated in the St. Jude Litigation. Thus, for each claim of the '119 Patent or any Subsequent Reissue Patent(s) that was Decided, Medtronic will not challenge validity or enforceability on any basis that was Decided as not being sufficient to render the claim invalid or unenforceable.

(i) For example, if the claims asserted in the St. Jude Litigation are Decided not to be unenforceable, then Medtronic would be precluded from challenging enforceability of those claims even though Medtronic would have or could have presented a different inequitable conduct defense.

(ii) For another example, if the claims asserted in the St. Jude Litigation are Decided not to be invalid under either 35 U.S.C. § 101, § 102 or § 103, Medtronic could not thereafter challenge validity of those claims under either 35 U.S.C. § 101, § 102 or § 103 (including newly discovered prior art) regardless of any differences in claim construction.

(iii) For another example, if the asserted claims in the St. Jude Litigation are Decided not to be invalid under 35 U.S.C. § 112 for lack of best mode, then Medtronic would not be precluded from challenging validity of those claims on the other individual non-adjudicated issues under 35 U.S.C. § 112 such as enablement or written description, but Medtronic would be precluded from challenging validity of those claims on the adjudicated best mode component of 35 U.S.C. § 112 even though Medtronic would have or could have presented a different best mode defense.

(b) Neither Party will be bound by the claim construction in the St. Jude Litigation, however, any Party may offer or argue for all or part of the claim construction in the St. Jude Litigation in the Final DJ Action.

(c) The parties agree to file in the Final DJ Action the Joint Proposed Stipulated Agreement attached as Exhibit A.

(d) Medtronic, its outside counsel and/or its in-house counsel shall be permitted to review documents produced by Mirowski and/or Guidant in the St. Jude litigation to the extent that these documents are reviewable, respectively, by St. Jude, its outside counsel and/or its in-house counsel pursuant to the protective order in the St. Jude litigation.

(e) For the '119 Patent and any Subsequent Reissue Patent(s), Guidant and Mirowski agree not to assert against Medtronic at any one time more than thirty patent claims in total. Additional claims may be asserted provided no more than thirty claims are asserted at any one time. This restriction shall not preclude Guidant and Mirowski from engaging in otherwise permissible discovery to ascertain which claims they wish to assert against Medtronic or seeking to add previously withdrawn claims as long as no more than thirty claims are asserted at any one time

10. Medtronic agrees to pay disputed royalties under the Medtronic Agreement for the Second Products and any Subsequent Products sold by Medtronic after October 31, 2004, as follows:

(a) Medtronic will accumulate disputed royalties and future disputed royalties in the amounts and at the times required by the Medtronic Agreement, together with interest at two (2) points above the prime rate as published in the Wall Street Journal compounded quarterly from the payment due date provided for in the Medtronic Agreement of such disputed royalties in the Medtronic/Mirowski Account.

(b) Medtronic will maintain in marketable securities, in an account with a financial institution of its choosing, the Medtronic/Mirowski Account and will provide a certified statement of the balance in said account on a quarterly basis, within ten (10) business days following the reports described in paragraph 10(c) below.

(c) Medtronic will render reports to Mirowski in accordance with the Medtronic Agreement on all sales for which disputed royalty payments are made to the Delaware Escrow Account and retained in the Medtronic/Mirowski Account. Medtronic shall further render a report of all accumulated royalties and accrued interest thereon. The reports shall be made at the same

> time as the disputed royalty payments would be due pursuant to the Medtronic Agreement.

11. Within thirty days after the final conclusion of the Final DJ Action, Medtronic will cause distribution of the total amount in the Medtronic/Mirowski account to Mirowski or to Medtronic in a manner consistent with the decision in the DJ Action. For example, if certain Medtronic products are held not to infringe the '119 Patent, but do infringe one or more Subsequent Reissue Patent(s), then Medtronic would be entitled to recover the portion of the Medtronic/Mirowski account for sales and interest prior to the issuance of the Subsequent Reissue Patent(s) while Mirowski would be entitled to recover the portion of the Medtronic/Mirowski account for sales and interest after the issuance of the Subsequent Reissue Patent(s) that Medtronic's products were held to infringe. Medtronic will continue to pay to Mirowski any further royalties due (if any) until expiration of the '119 patent. In the event Mirowski alleges that Medtronic is in breach of any of its obligations under this paragraph 11, and if the court in any action against Medtronic for such breach rules in favor of Mirowski, then Medtronic shall reimburse Guidant and/or Mirowski for all of it's or their attorney's fees and other costs incurred in prosecuting such action.

* * *

15. Except for the August 28, 2003 Settlement Agreement, the Medtronic Agreement, and the Amended Original Agreement, this Agreement constitutes the entire agreement and understanding of the Parties with regard to the subject matter hereof and merges and supersedes all prior discussions, negotiations, understandings and agreements among the Parties concerning the subject matter hereof. The Medtronic

Agreement shall be considered to be amended as necessary to conform with this Agreement.

16. This Agreement shall be interpreted and construed, and the legal relations created herein shall be determined, in accordance with the laws of the State of Minnesota and the United States.

* * *

IN WITNESS WHEREOF, the parties hereto have set their hands and seals the day and year written below.

Mirowski Family Ventures, LLC

By /s/ Ginat W. Mirowski

Ginat W. Mirowski, D.M.D., M.D.
General Manager and President
Date 7/18/06

Guidant Corporation

By /s/ Richard S. Vogel
Name Richard S. Vogel
Title VP & CFO
Date 7/13/06

Medtronic, Inc.

By /s/ Stephen H. Mahle

Stephen H. Mahle
Executive Vice President & President, CRDM
Date 6.30.06

* * *

[letterhead omitted]

October 3, 2007

via FedEx

Medtronic, Inc.
710 Medtronic Parkway, MS LC 340
Minneapolis, MN 55432-5604

Attn: General Counsel

Dear General Counsel:

In accordance with paragraph 7(c) of the Litigation Tolling Agreement, Mirowski Family Ventures, LLC ("MFV") provides notice that Medtronic, Inc.'s ("Medtronic") InSync ICD, InSync II Marquis, InSync Maximo, InSync, InSync Sentry, InSync Protect, and Concerto products infringe at least one of claims 15-26 of U.S. Patent No. RE38,119 ("the '119 patent"). In providing this notice, MFV assumes that Medtronic has complied with the Litigation Tolling Agreement, particularly paragraphs 7(a) and 7(b), and reserves the right to modify this notice.

In addition, MFV notes Application No. 10/214,474 ("the '474 application") that claims priority to the '119 patent has not yet issued. Because MFV is not required under the Litigation Tolling Agreement to give notice of the claims of the '474 application until it actually issues, MFV intends to identify claims of the '474 application once it does issue.

Very truly yours,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

/s/ Arthur I. Neustadt

Arthur I. Neustadt

AIN:dlg

[letterhead omitted]

November 20, 2007

via FedEx

Medtronic, Inc.
710 Medtronic Parkway, MS LC 340
Minneapolis, MN 55432-5604

Attn: General Counsel

Dear General Counsel:

As you know, in accordance with paragraph 7(c) of the Litigation Tolling Agreement ("the Agreement"), Mirowski Family Ventures, LLC ("MFV") provided notice on October 3, 2007, that Medtronic Inc.'s ("Medtronic") InSync ICD, InSync II Marquis, InSync Maximo, InSync, InSync Sentry, InSync Protect, and Concerto products infringe at least one of claims 15-26 of U.S. Patent No. RE38,119 ("the '119 patent"). MFV hereby amends that notice and provides notice that Medtronic's InSync ICD, InSync II Marquis, InSync Maximo, InSync, InSync Sentry, InSync Protect, and Concerto products infringe at least one of claims 15, 19, 20, and 26 of the '119 patent and claims 120, 162, 172, 184, 201, 211, 217, 225, 233, 248, 273, 282, 288, 294, 303, 308, 309, 314, 315, 320, and 324-328 of U.S. Patent No. RE39,897.

The claims that are asserted may change as set forth in paragraph 9(c) of the Agreement.

In providing this notice, MFV assumes that Medtronic has complied with the Agreement, particularly paragraphs 7(a) and 7(b). In that regard, MFV notes that Medtronic has only identified two products (i.e., the InSync Protect and Concerto products) since the effective date of the Agreement.

Very truly yours,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

/s/ Arthur I. Neustadt

Arthur I. Neustadt

AIN:dlg

cc: Jeanne M. Forneris, Esq.
Thomas G. Berry, Esq.
Richard Clapp, Esq.

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

MEDTRONIC, INC., a Minnesota corporation, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, a Delaware corporation, GUIDANT CORPORATION, an Indiana Corporation and MIROWSKI FAMILY VENTURES L.L.C., a Maryland limited liability corporation, Defendants.	)	Civil Action No. Jury Trial Demanded

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Medtronic, Inc., as and for its Complaint herein, states as follows:

* * *

FACTUAL BACKGROUND

* * *

12. On May 13, 1991, Medtronic entered into a Settlement and License Agreement with Lilly and CPI to settle several lawsuits between the three companies regarding various patents related to implantable pacemakers and defibrillators. On May 24, 1991, the parties entered into an Omnibus Amendment of the Settlement and License Agreement. These agreements were fur-

ther amended by Letter Agreement dated April 14, 2003 (collectively "the Agreement"). As part of the Agreement, Medtronic obtained a license under a number of patents, including the '688 Patent. Medtronic also obtained a license to all patents that matured from continuations of the '688 Patent or reissues of the '688 Patent.

* * *

15. Under Article III of the Agreement, if Mirowski and its exclusive licensee believe that a new Medtronic device infringes one or more claims of the patents licensed under the Agreement and Medtronic is not paying royalties on such new device, then Mirowski and its exclusive licensee must notify Medtronic of the alleged infringement. Medtronic shall then have an opportunity to cure the nonpayment of royalties and challenge the assertion of infringement through a declaratory judgment action.

* * *

19. Medtronic, Mirowski and Guidant entered into a Litigation Tolling Agreement in July 2006.

20. Under the terms of the Litigation Tolling Agreement, the parties agreed to a Declaratory Judgment Suspension period ("DJ Suspension Period") of no later than October 1, 2007. Within sixty (60) days after the expiration of the DJ Suspension Period, the parties agreed that Guidant or Mirowski must provide Medtronic with notice—in writing—of products they believe infringe no more than 30 claims of the '119 Reissue Patent or subsequent reissue patent. As required by the Tolling Agreement, a Joint Proposed Stipulated Agreement is attached to the Complaint as Exhibit C.

* * *

23. Under the terms of the Litigation Tolling Agreement, the parties agreed that within ninety (90) days after receiving notice of infringement from Mirwoski or Guidant, Medtronic may initiate a Final DJ action in the District of Delaware, challenging infringement, unenforceability and/or validity of the '119 Reissue Patent and any asserted claims of any subsequent reissue patent.

* * *

26. Based on the facts described above, Medtronic is entitled to file this action seeking the declaratory relief demanded in this Complaint.

* * *

[letterhead omitted]

December 4, 2008

VIA FACSIMILE

Arthur I. Neustadt, Esq.
Oblon, Spivak, McClelland, Maier & Neustadt, P.C.
1940 Duke Street
Alexandria, VA 22314

Re: Medtronic, Inc. v. Mirowski, et al
Our File No.: 026118.0038

Dear Arthur:

I write in response to your email dated December 1, 2008 regarding the burden of proof on the issue of infringement.

Medtronic disagrees with the defendants' recently-stated position that they have no burden, and hence, no obligation to set forth their contentions regarding their infringement assertions at this time. First, this case was brought based on the defendants' allegations of infringement. On November 20, 2007, Mirowski Family Ventures specifically asserted that certain Medtronic products "infringe at least one claim" of the '119 and '897 patents. In addition, in its Answer to the Complaint, both Mirowski and Boston Scientific "admit" that MFV "alleges that certain of Medtronic's implantable cardiac stimulation devices infringe at least one" claim of the '119 and '897 patents. Answers ¶ 7, respectively. As such, it is incorrect to argue that the defendants, the patent holder who charged Medtronic with infringement, have no burden on that issue

I note that last week was the first time that the defendants raised its belief that Medtronic bears the burden on this issue. Indeed, the defendants' new position is contrary to the discussions between the parties during the Rule 26(f) conference as well as the understanding of the parties as they worked towards the proposed Scheduling Order that was submitted to the Court. This is also in contradiction with other representations that defendants have made in this case. For example, in your letter of September 9, 2008, you stated your concern that the 30(b)(6) deposition of Medtronic regarding the operation of the accused products must go forward on November 12, based on the deadline for contention interrogatories (November 28, 2008). Because of that stated concern, Medtronic assured the defendants it would provide a witness prior to the deadline for the defendants' infringement contentions (my letter to you, dated September 22, 2008).

Finally, your assertion that the defendants do not carry the burden on this issue is belied by the fact that the defendants felt the need to provide a submission with regard to infringement on December 1, the agreed-upon date for the mutual exchange of contention interrogatory answers. While the defendants did not provide detailed infringement contentions, and instead chose to provide a "Submission Concerning Claim Coverage," Medtronic will treat that submission as the defendants' infringement contentions. As such, pursuant to the Scheduling Order, Medtronic's response will be contain the same "level of detail ... i.e., the more detail a party provides, the more detail a party shall receive." Scheduling Order, p. 4.

Very truly yours,

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

/s/ Stacie Oberts

Stacie E. Oberts

SEO/jw

cc: J. Michael Jakes, Esq. *(via facsimile)*
Naveen Modi, Esq. *(via facsimile)*

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

MEDTRONIC, INC., a Minnesota corporation,)
)
Plaintiff,)
)
v.) Civil Action No. 07-823-SLR
)
BOSTON SCIENTIFIC CORPORATION, a Delaware corporation, GUIDANT CORPORATION, an Indiana corporation and MIROWSKI FAMILY VENTURES L.L.C., a Maryland limited liability corporation,) Jury Trial Demanded
)
Defendants.)
)

SECOND AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Medtronic, Inc., as and for its Complaint herein, states as follows:

* * *

FACTUAL BACKGROUND

* * *

7. Boston Scientific, Guidant and Mirowski allege that certain of Medtronic's implantable cardiac stimulation devices infringe "at least one of" claims 15, 19, 20 and 26 of the '119 Reissue Patent, and claims 120, 162, 172, 184, 201, 211, 217, 225, 233, 248, 273, 282, 288, 294,

303, 308, 309, 314, 315, 320 and 324-328 of the '897 Reissue Patent, entitled "Method and Apparatus for Treating Hemodynamic Disfunction."

* * *

15. Under Article III of the Agreement, if Mirowski and its exclusive licensee believe that a new Medtronic device infringes one or more claims of the patents licensed under the Agreement and Medtronic is not paying royalties on such new device, then Mirowski and its exclusive licensee must notify Medtronic of the alleged infringement. Medtronic shall then have an opportunity to cure the nonpayment of royalties and challenge the assertion of infringement through a declaratory judgment action.

* * *

21. By letter on October 3, 2007 Mirowski informed Medtronic that Medtronic's InSync ICD, InSync II Marquis, InSync Maximo, InSync II Protect, InSync, InSync Sentry and Concerto devices ("the Accused Devices") infringe "at least one" of claims 15-26 in the '119 Reissue Patent, and that it intended to identify additional claims that issued from the '474 Application once the claims issued. On November 20, 2007, Mirowski informed Medtronic that at least one of claims 15, 19, 20 and 26 of the '119 are infringed by the Accused Devices.

22. By letter on November 20, 2007, Mirowski informed Medtronic that the Accused Devices infringe claims 120, 162, 172, 184, 201, 211, 217, 225, 233, 248, 273, 282, 288, 294, 303, 308, 309, 314, 315, 320 and 324-328 of the '897 Reissue Patent.

23. By letter on October 27, 2008, Mirowski informed Medtronic that claims 15, 19, 20 and 26 of the '119 Reissue Patent and claims 120, 162, 172, 184, 201,

211, 217, 225, 233, 248, 273, 282, 288, 294, 303, 308, 309, 314, 315, 320 and 324-328 of the '897 Reissue Patent are also infringed by Medtronic's Maximo® II CRT-D D284TRK ("Maximo II") and Consulta™ CRT-D D224TRK ("Consulta") products. Thus, "the Accused Devices" as of October 27, 2008 are Medtronic's InSync ICD, InSync II Marquis, InSync Maximo, InSync II Protect, InSync, InSync Sentry, Concerto, Maximo II and Consulta devices.

24. By letter on December 31, 2008, Mirowski informed Medtronic that it was withdrawing claims 162, 211, 225, 282, 294, 314 and 320 of the '897 Reissue Patent, and that it was asserting claim 25 of the '119 Reissue Patent and claims 15, 54, 84, 86, 144 and 311 of the '897 Reissue Patent.

25. Under the terms of the Litigation Tolling Agreement, the parties agreed that within ninety (90) days after receiving notice of infringement from Mirowski or Guidant, Medtronic may initiate a Final DJ action in the District of Delaware, challenging infringement, unenforceability and/or validity of the '119 Reissue Patent and any asserted claims of any subsequent reissue patent.

* * *

COUNT ONE
DECLARATORY JUDGMENT OF NON-INFRINGEMENT BY THE ACCUSED DEVICES OF THE '119 REISSUE PATENT

30. Medtronic hereby restates and realleges the allegations set forth in paragraphs 1-29.

31. Defendants have asserted that the Accused Devices infringed and continue to infringe claims 15, 19,

20, 25 and 26 of the '119 Reissue Patent, creating an actual controversy within this Court's jurisdiction.

32. Medtronic's Accused Devices do not infringe, either directly or indirectly, contributorily, by inducement or otherwise, any valid and enforceable claim of the '119 Reissue Patent.

33. Medtronic is entitled to a declaration that the Accused Devices do not infringe any valid and enforceable claim of the '119 Reissue Patent.

COUNT TWO
DECLARATORY JUDGMENT OF INVALIDITY OF THE ASSERTED CLAIMS OF THE '119 REISSUE PATENT

34. Medtronic hereby restates and realleges the allegations set forth in paragraphs 1-29.

35. Each Asserted Claim of the '119 Reissue Patent is invalid because it does not meet one or more of the conditions for patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, 132, 251 *et seq.*

36. Medtronic is entitled to a declaration that the Asserted Claims of the '119 Reissue Patent are invalid.

COUNT THREE
DECLARATORY JUDGMENT OF NON-INFRINGEMENT BY THE ACCUSED DEVICES OF THE '897 REISSUE PATENT

37. Medtronic hereby restates and realleges the allegations set forth in paragraphs 1-29.

38. Defendants have asserted that the Accused Devices infringed and continue to infringe claims 15, 54, 84, 86, 120, 144, 172, 184, 201, 217, 233, 248, 273, 288, 303, 308, 309, 311, 315 and 324-328 of the '897 Reissue

Patent, creating an actual controversy within this Court's jurisdiction.

39. Medtronic's Accused Devices do not infringe, either directly or indirectly, contributorily, by inducement or otherwise, any valid and enforceable claim of the '897 Reissue Patent.

40. Medtronic is entitled to a declaration that the Accused Devices do not infringe any valid and enforceable claim of the '897 Reissue Patent.

COUNT FOUR
DECLARATORY JUDGMENT OF INVALIDITY OF THE ASSERTED CLAIMS OF THE '897 REISSUE PATENT

41. Medtronic hereby restates and realleges the allegations set forth in paragraphs 1-29.

42. Each Asserted Claim of the '897 Reissue Patent is invalid because it does not meet one or more of the conditions for patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, 132, 251 *et seq.*

43. Medtronic is entitled to a declaration that the Asserted Claims of the '897 Reissue Patent are invalid.

COUNT FIVE
DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE ASSERTED CLAIMS OF THE '119 REISSUE PATENT

44. Medtronic hereby restates and realleges the allegations set forth in paragraphs 1-29.

45. The '119 Reissue Patent issued after unreasonable delay during prosecution.

46. Each Asserted Claim of the '119 Reissue Patent is unenforceable under the doctrine of prosecution laches.

47. Medtronic is entitled to a declaration that the Asserted Claims of the '119 Reissue Patent are unenforceable.

COUNT SIX
DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE ASSERTED CLAIMS OF THE '897 REISSUE PATENT

48. Medtronic hereby restates and realleges the allegations set forth in paragraphs 1-29.

49. The '897 Reissue Patent issued after unreasonable delay during prosecution.

50. Each Asserted Claim of the '897 Reissue Patent is unenforceable under the doctrine of prosecution laches.

51. Medtronic is entitled to a declaration that the Asserted Claims of the '897 Reissue Patent are unenforceable.

WHEREFORE, Medtronic prays for judgment as follows:

1. A declaration that Medtronic has not infringed and is not infringing, either directly, indirectly, contributorily or otherwise, any valid and enforceable claim of the '119 Reissue Patent or '897 Reissue Patent by its manufacture, sale, offer for sale, or use of the Accused Devices.

2. A declaration that the Asserted Claims of the '119 Reissue Patent and '897 Reissue Patent are invalid.

3. A declaration that the Asserted Claims of the '119 Reissue Patent and '897 Reissue Patent are unenforceable under the doctrine of prosecution laches.

4. That Medtronic be awarded its costs, disbursements and attorneys' fees herein in accordance with the terms of the Agreement and with Title 35 U.S.C. § 285; and

5. That Medtronic be awarded such other and further relief as this Court may deem just and proper.

* * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDTRONIC, INC.,)
Plaintiff,)
)
v.)
) C.A. No. 07-823-SLR-LPS
BOSTON SCIENTIFIC)
CORPORATION, GUI-)
DANT CORPORATION and)
MIROWSKI FAMILY)
VENTURES, L.L.C.,)
Defendants.)
)

SECOND AMENDED ANSWER AND COUNTERCLAIM OF MIROWSKI FAMILY VENTURES, L.L.C.

RESPONSE TO SECOND AMENDED COMPLAINT

Defendant Mirowski Family Ventures L.L.C. ("MFV") responds to the Second Amended Complaint filed by plaintiff Medtronic, Inc. ("Medtronic") as follows.

* * *

Factual Background

* * *

7. As of December 31, 2008, MFV alleges that certain of Medtronic's implantable cardiac stimulation devices infringe at least one of claims 15, 19, 20, 25, and 26 of the '119 patent and claims 15, 54, 84, 86, 120, 144, 172, 184, 201, 217, 233, 248, 273, 288, 303, 308, 309, 311, 315, and 324-328 of the '897 patent. MFV admits that the '119 and '897 patents are entitled "Method and Ap-

paratus for Treating Hemodynamic Disfunction." Except as expressly admitted, MFV denies the allegations of paragraph 7.

* * *

21. MFV admits the allegations of paragraph 21 except that "InSync II Protect" is assumed to refer to "InSync Protect."

22. MFV admits that by letter on November 20, 2007, it informed Medtronic that Medtronic's InSync ICD, InSync II Marquis, InSync Maximo, InSync, InSync Sentry, InSync Protect, and Concerto products infringe at least one of claims 120, 162, 172, 184, 201, 211, 217, 225, 233, 248, 273, 282, 288, 294, 303, 308, 309, 314, 315, 320, and 324-328 of the '897 patent. Except as expressly admitted, MFV denies the allegations of paragraph 22.

23. MFV admits the allegations of paragraph 23 except that "InSync II Protect" is assumed to refer to "InSync Protect."

24. MFV admits the allegations of paragraph 24.

* * *

Count I

* * *

31. MFV admits that it has asserted that Medtronic's InSync ICD, InSync II Marquis, InSync Maximo, InSync, InSync Sentry, InSync Protect, Concerto, Maximo II and Consulta products infringe at least one of claims 15, 19, 20, 25 and 26 of the '119 patent, and that there is an actual controversy within this Court's jurisdiction. Except as expressly admitted, MFV denies the allegations of paragraph 31.

* * *

Count III

* * *

38. MFV admits that it has asserted that Medtronic's InSync ICD, InSync II Marquis, InSync Maximo, InSync, InSync Sentry, InSync Protect, Concerto, Maximo II and Consulta products infringe at least one of claims 15, 54, 84, 86, 120, 144, 172, 184, 201, 217, 233, 248, 273, 288, 303, 308, 309, 311, 315, and 324-328 of the '897 patent, and that there is an actual controversy within this Court's jurisdiction. Except as expressly admitted, MFV denies the allegations of paragraph 38.

* * *

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

MEDTRONIC, INC.,
Plaintiff,
v.
BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, and MIROWSKI FAMILY VENTURES L.L.C.,
Defendants.

C.A. No. 07-823-SLR
Delaware District Court

PROPOSED PRETRIAL ORDER

* * *

The following matters as to the trial are hereby ordered by the Court:

I. NATURE OF THE ACTION AND THE PLEADINGS

A. Nature of the Action

Medtronic has been a licensee of the predecessors of defendants since May 13, 1991 with respect to the Mirowski patent portfolio. This license agreement "provided that Medtronic could challenge validity and infringement … without breaching the license, provided that Medtronic filed a declaratory judgment action and paid the royalties that would otherwise be due into an escrow account." D.I. 86 at 2. In July 2006 Medtronic, MFV and Guidant executed a litigation tolling agreement ("LTA") "providing that Medtronic would file a declaratory judgment action in Delaware on the

'119 and '897 reissue patents." D.I. 86 at 6-7.[1] Medtronic agreed to pay disputed royalties into an escrow account and these royalties would be distributed consistent with the decision in the declaratory judgment action. D.I. 86 at 7. This suit is that declaratory judgment action.

In this action, pursuant to the LTA, Medtronic requests a declaration that (1) the asserted claims of the '119 and '897 patents are not infringed by the designated Medtronic products, (2) these claims are not patentable over the prior art and (3) these claims are unenforceable due to prosecution laches.

* * *

IV. PRETRIAL ORDER TO CONTROL FUTURE PROCEEDINGS

This Order shall control the subsequent course of the action unless modified by the Court to prevent manifest injustice.

* * *

---

[1] The term "infringement" is used in the LTA to indicate claim coverage. Since Medtronic is a licensee, it cannot be an infringer.

UNITED STATES DISTRICT COURT DISTRICT OF DELAWARE

MEDTRONIC, INC., Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, and MIROWSKI FAMILY VENTURES, L.L.C., Defendants.	Case No. 07-823-SLR Contains Confidential, Outside Counsel's Eyes Only Information[*]

EXHIBIT 1 TO PRETRIAL ORDER

STATEMENT OF FACTS WHICH ARE ADMITTED AND REQUIRE NO PROOF

Plaintiff and Defendants stipulate to the following admitted facts that require no proof.

I. The Patents-In-Suit

* * *

9. The claims at issue are claims 15, 19, 20, 25 and 26 of the '119 patent and claims 15, 54, 84, 86, 120, 144, 172, 184, 201, 217, 233, 248, 273, 288, 303, 308, 309, 311, 315 and 324-328 of the '897 patent as covered by a license to Medtronic.

* * *

[* The material excerpted in this Joint Appendix is not confidential.]

III. The Defendants

* * *

14. Defendants BSC and Guidant are the exclusive licensees and plaintiff Medtronic is a non-exclusive licensee of the '119 patent and the '897 patent.

IV. Medtronic's Products

15. Pursuant to the LTA, the Medtronic products asserted to infringe are InSync ICD, InSync II Marquis, InSync Maximo, InSync, InSync Sentry, InSync II Protect, Concerto, Maximo II and Consulta products.

16. Under a July 2006 litigation tolling agreement between the parties, Medtronic states that it has deposited disputed royalties on the products into a Medtronic/Mirowski account as to which MFV does not have access. Medtronic states that it has deposited monies representing 3% of revenues from the designated products from November 1, 2004 through January 23, 2009, when the patents-in-suit expired. The outcome of trial will determine how those monies are distributed.

17. Medtronic has agreed that if its Concerto product infringes any valid and enforceable claim of the '119 or '897 patents, its Maximo II and Consulta products would also infringe. See S. Oberts 1/16/09 letter.

* * *

Medtronic's Devices Do Not Infringe The Asserted Claims of the '119 Patent

Claim Limitation [illegible]	'119 Claim [illegible]	'119 Claim 19	'119 Claim 20	'119 Claim 25	'119 Claim [illegible]
Immediately	✓			✓	✓
Unconditionally	✓			✓	✓
Sensing/detecting a contraction		✓	✓	✓	✓
Sensing in the atria		✓	✓		
Predetermined AV delay		✓	✓		
Into the left ventricle			✓		

Plaintiff's
Trial Exhibit
PX 561A
C.A. 07-823 SLR

PETITIONER'S BRIEF

Supreme Court, U.S.
FILED
JUL 26 2013
OFFICE OF THE CLERK

No. 12-1128

IN THE
Supreme Court of the United States

MEDTRONIC, INC.,
Petitioner,
v.

BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, AND MIROWSKI FAMILY VENTURES, LLC,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR PETITIONER

MARTIN R. LUECK
Counsel of Record
JAN M. CONLIN
STACIE E. OBERTS
ROBINS, KAPLAN, MILLER & CIRESI LLP
2800 LaSalle Plaza
800 LaSalle Ave.
Minneapolis, MN 55402
(612) 349-8500
mrlueck@rkmc.com

SETH P. WAXMAN
PAUL R. Q. WOLFSON
BRIAN H. FLETCHER
CAROLYN JACOBS CHACHKIN
WEILI J. SHAW
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006

MARK C. FLEMING
WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109

QUESTION PRESENTED

In *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 137 (2007), this Court ruled that a patent licensee that believes that its products do not infringe the patent and accordingly are not subject to royalty payments is "not required … to break or terminate its … license agreement before seeking a declaratory judgment in federal court that the underlying patent is … not infringed."

The question presented is whether, in such a declaratory judgment action brought by a licensee under *MedImmune*, the licensee has the burden to prove that its products do *not* infringe the patent, or whether (as in all other patent litigation, including other declaratory judgment actions), the patentee must prove infringement.

PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT

There are no parties to the proceedings other than those listed in the caption.

Petitioner Medtronic, Inc. has no parent corporations and no publicly held company owns 10% or more of its stock.

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IN THE
Supreme Court of the United States

No. 12-1128

MEDTRONIC, INC.,
Petitioner,
v.
BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, AND MIROWSKI FAMILY VENTURES, LLC,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR PETITIONER

INTRODUCTION

When a party accused of patent infringement responds by seeking a declaratory judgment that the patent is invalid or not infringed, the nominal status of the parties is reversed: The patentee (who would have been the plaintiff in any traditional suit for infringement damages or an injunction) becomes the declaratory judgment defendant, while the accused infringer becomes the plaintiff. Such role reversal is commonplace in declaratory actions. Indeed, one of the principal purposes of the Declaratory Judgment Act was to allow "prospective defendants to sue to establish their nonliability." *Beacon Theatres, Inc.* v. *Westover*, 359 U.S.

500, 504 (1959). The question presented here is whether this nominal change in party status shifts the burden of proof on the question of infringement from the patentee, which would have borne the burden in a traditional suit, to the accused infringer.

In the decision below, the Federal Circuit acknowledged the well established principle that "mere role reversal in a declaratory judgment action does not shift the burden." Pet. App. 11a. But it believed that a different rule applies when, as authorized by *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118 (2007), a patent licensee in good standing seeks a declaration that its products do not infringe the licensed patent. In *MedImmune*-type cases, the Federal Circuit held, the burden shifts to the licensee, which must prove that its products do *not* infringe.

The Federal Circuit's creation of a special burden-shifting rule in *MedImmune*-type cases was error. It departed from the overwhelming weight of authority regarding the allocation of the burden of proof in declaratory actions. And by allowing the nominal reversal of parties in a declaratory action to dictate the assignment of the burden, the Federal Circuit also contradicted this Court's precedents emphasizing that the Declaratory Judgment Act "is procedural only," *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 240 (1937), whereas the allocation of the burden of proof "inhere[s]" in the governing substantive law and "cannot be considered a mere incident of a form of procedure," *Garrett* v. *Moore-McCormack Co.*, 317 U.S. 239, 249 (1942). Finally, the Federal Circuit's novel rule improperly penalizes the use of the declaratory judgment procedure and frustrates the purposes of the Declaratory Judgment Act. Congress intended to allow a declaratory judgment plaintiff to obtain a judicial resolution of the same issues that would have been presented had its counterparty filed a coercive suit. But under the Federal Circuit's rule, the substantive issue presented in the declaratory action would differ in an important and potentially outcome-determinative respect.

The decision below should be reversed. Consistent with this Court's precedent and the Declaratory Judgment Act, the burden in *MedImmune*-type suits should remain where the substantive patent law places it—on the patent holder asserting infringement.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-18a) is reported at 695 F.3d 1266. The order of the court of appeals denying rehearing and rehearing en banc (*id.* 84a-86a) is unreported. The opinion of the district court (*id.* 19a-83a) is reported at 777 F. Supp. 2d 750.

JURISDICTION

This Court has jurisdiction under 28 U.S.C. § 1254(1). The court of appeals entered judgment on September 18, 2012 and denied rehearing on December 14, 2012. The petition for certiorari was filed on March 14, 2013, and granted on May 20, 2013.

STATUTORY PROVISIONS INVOLVED

1. The Patent Act of 1952 provides: "A patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281.

2. The Declaratory Judgment Act of 1948 provides in relevant part:

> In a case of actual controversy within its jurisdiction, ... any court of the United States, upon

> the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

28 U.S.C. § 2201(a).

> Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.

Id. § 2202.

STATEMENT

A. The Declaratory Judgment Act

Before the early 20th century, declaratory relief was generally unavailable in American courts. As a result, parties who found themselves embroiled in a legal dispute could not bring the matter before a court unless and until one of them did something to give the other a right to bring a traditional coercive action for money damages or an injunction—for example, by breaching a disputed contract. And even after a coercive suit became ripe, if the party with the right to sue failed to do so promptly, its counterparty could be left uncertain about its rights and exposed to growing potential liability, but without any judicial recourse.

In 1934, Congress enacted the Declaratory Judgment Act to allow parties in these circumstances to obtain a definitive adjudication of their rights without disrupting legal relationships or subjecting themselves to legal peril. The Act provides that, "[i]n a case of actual controversy within its jurisdiction," a federal court may "declare the rights and other legal relations" of the parties "whether or not further relief is or could be sought." 28 U.S.C. § 2201(a).

The passage of the Act followed more than a decade of advocacy by the American Bar Association, legal scholars, and other reformers. One of their central arguments was that a party faced with an assertion of liability should not have to risk a damages award or await a suit filed at a time of its opponent's choosing to obtain certainty about its rights. As one of the leading proponents of the Act explained in a 1928 Senate hearing on an earlier version of the law, patent cases were a paradigmatic example of this problem:

> I assert that I have a right to use a certain [device]. You claim that you have a patent. What am I going to do about it? There is no way that I can litigate my right ... to use that device, except by going and using it, and you can sit back as long as you please and let me run up just as high a bill of damages as you wish to have me run up, and then you may sue me for the damages, and I am ruined, having acted all the time in good faith and on my best judgment, but having no way in the world to find out whether I had a right to use that device or not.

Declaratory Judgments: Hearings on H.R. 5623 Before a Subcomm. of the S. Comm. on the Judiciary, 70th Cong. 35 (1928) (statement of Professor E.R. Sunderland). Professor Edwin Borchard, whom this Court has often cited as an authority on the Declaratory Judgment Act,[1] made a similar point in his preeminent treatise on the subject: "As the law stood prior to 1934, ... the patentee was the only one in a position to initiate a suit, usually an action for damages" and "the alleged infringer was helpless" because he was "forced by the law to await the pleasure of the patentee in bringing the validity of his patent and the charge of infringement to judicial test." Borchard, *Declaratory Judgments* 803 (2d ed. 1941).

The Declaratory Judgment Act was intended to address this problem by allowing potential patent infringers and others faced with concrete accusations of liability to seek a definitive determination of their rights without risking a damages award or waiting for their accusers to sue. Rather than committing a potentially infringing act, for example, an accused infringer can seek a declaratory judgment that the patent is invalid or would not be infringed by the contemplated conduct. Critically, Congress envisioned that this sort of declaratory action would raise the "same question" as the coercive suit it anticipated:

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[1] *See Franchise Tax Bd. of Cal.* v. *Construction Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 17 n.15 (1983) (describing Professor Borchard as "the leading proponent of declaratory judgments"); *Steffel* v. *Thompson*, 415 U.S. 452, 468 n.18 (1974) (citing Professor Borchard as "a principal proponent and author of the Federal Declaratory Judgment Act"); *id.* at 477 (White, J., concurring) (describing Professor Borchard as "eminent authority" on the Act); *see also, e.g.*, *Wilton* v. *Seven Falls Co.*, 515 U.S. 277, 286-289 (1995); *Hewitt* v. *Helms*, 482 U.S. 755, 763 (1987); *Bob Jones Univ.* v. *Simon*, 416 U.S. 725, 733 n.7 (1974); *Abbott Labs.* v. *Gardner*, 387 U.S. 136, 152 n.18 (1967); *Rabinowitz* v. *Kennedy*, 376 U.S. 605, 607 n.1 (1964); *Public Serv. Comm'n of Utah* v. *Wycoff Co.*, 344 U.S. 237, 243 nn.4-5 (1952); *Eccles* v. *Peoples Bank of Lakewood Vill.*, 333 U.S. 426, 431 (1948); *Altvater* v. *Freeman*, 319 U.S. 359, 363 n.3, 365 (1943); *Great Lakes Dredge & Dock Co.* v. *Huffman*, 319 U.S. 293, 300 (1943).

> You have the same court, the same jurisdiction, the same procedure, the same parties and the same question. Under the present law you take a step in the dark and then turn on the light to see if you stepped into a hole. Under the declaratory judgment law you turn on the light and then take the step.

S. Rep. No. 73-1005, at 3 (1934) (internal quotation marks omitted).[2]

As required by Article III of the Constitution, the courts' authority to adjudicate cases under the Declaratory Judgment Act is limited to "case[s] of actual controversy." 28 U.S.C. § 2201(a). But as long as there is "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality," *Maryland Cas. Co.* v. *Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941), the Act allows the disputing parties to obtain a judicial resolution of issues that otherwise would have had to await a coercive action, with all the attending uncertainty, disruption, and expense.

B. This Court's *MedImmune* Decision

This Court's decision in *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118 (2007), confirmed that the clarity and certainty afforded by the Declaratory

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[2] *See also*, S. Rep. No. 73-1005, at 3 ("Persons now often have to act at their peril, a danger which could be frequently avoided by the ability to sue for a declaratory judgment as to their rights or duties."); *id.* at 2 (the declaratory judgment procedure enables "parties in disputes over their rights over a contract" to "sue for a declaration of rights, *without* breach of the contract" (emphasis added)).

Judgment Act are available to a patent licensee who believes that the licensed patent is invalid, unenforceable, or not infringed by the licensee's products. *MedImmune* made clear that a licensee in that situation need not subject itself to the peril of a damages action by the patentee, but may obtain a definitive clarification of its legal situation by invoking the declaratory judgment remedy without breaching the license.

MedImmune had licensed a patent and a pending patent application from Genentech. *MedImmune*, 549 U.S. at 121. In 2001, after the licensed application matured into a patent, Genentech sent MedImmune a letter asserting that a particular MedImmune drug was covered by the newly issued patent and demanding payment of royalties. *Id.* at 121-122. MedImmune brought suit seeking a declaration that the patent was invalid and not infringed, and thus that it had no duty to pay the royalties demanded by Genentech. *Id.* at 122-125 & n.6. But MedImmune also continued to pay royalties under protest during the pendency of the lawsuit to avoid potentially breaching the license agreement. *Id.* at 128. The Federal Circuit held that the presence of the license agreement deprived the federal courts of jurisdiction under Article III of the Constitution, reasoning that "a patent licensee in good standing cannot establish an Article III case or controversy with regard to validity, enforceability, or scope of the patent" because the license eliminates any risk that the licensee will be sued for infringement. *Id.* at 122.

This Court reversed. The Court held that, when a declaratory judgment plaintiff faces a concrete and realistic threat of enforcement from the defendant, the fact that the plaintiff refrains from actions that it would otherwise take (or takes action that it would otherwise not take) is sufficient to establish an Article III case or controversy. *See MedImmune*, 549 U.S. at 129-134. As the Court explained, that is precisely the situation when a patent holder demands royalties under a license and the licensee pays under protest while seeking a declaration that the patent is invalid, unenforceable, or not infringed: The license payments are effectively coerced by the threat that, if the licensee stops paying, it will incur liability for patent infringement or breach of the license. *See id.* at 130 & n.9. *MedImmune* made clear that a licensee can dispel that uncertainty and obtain a definitive resolution of the parties' disputed legal rights without risking liability.

C. The License Agreements In This Case

Petitioner Medtronic designs, manufactures, and sells innovative products used to treat medical disorders. Medtronic's products include implantable cardiac stimulation devices, which help a patient maintain a normal heart rate or rhythm.

In 1991, Medtronic entered into a broad cross-license with Eli Lilly & Co. involving large portfolios of patents. JA7-18. This agreement included a sublicense to Medtronic of certain cardiac stimulation device patents that were owned by Respondent Mirowski Family Ventures, LLC ("MFV") and exclusively licensed to Lilly. JA8-9, 12-13. Medtronic's sublicense provided that if MFV or Lilly believed that any new Medtronic products infringed a patent covered by the sublicense, Lilly would provide a notice asserting infringement to Medtronic. JA13. Upon receipt of such a notice, Medtronic had the right to pay the demanded royalties under protest and to bring a "Declaratory Judgment action" challenging "the validity and enforceability of any patent under the Mirowski license, other than" five patents not at issue here, as well as the "assertion of infringement of any of the Mirowski patents." *Id.*

In 2003, another patent covered by the sublicense, U.S. Reissue Patent RE38,119 ("the '119 patent"), issued and was assigned to MFV. In 2004, Respondent Guidant Corporation succeeded to Eli Lilly's exclusive license.[3] In 2006, Medtronic, Guidant, and MFV signed a Litigation Tolling Agreement ("LTA"). The LTA began with an express recognition that "an actual controversy exists between and among the Parties under 35 U.S.C. § 271 as to the scope, validity and enforceability of the '119 Patent." JA20. The agreement then reaffirmed both MFV's obligation to inform Medtronic of any contentions of infringement under the '119 patent and Medtronic's right to challenge those assertions through a declaratory judgment action. JA23-24.

The LTA provided that Medtronic would maintain an amount (including interest) sufficient to pay any royalties that would be due on products that MFV asserted infringed the licensed patents and required Medtronic to make quarterly certifications to MFV as to the availability of the accumulated amount. JA27-28. Upon conclusion of the declaratory judgment action, the LTA requires Medtronic to distribute the funds "in a manner consistent with the decision in the DJ Action." JA28.

D. MFV's Assertions Of Infringement

On October 3, 2007, MFV's litigation counsel sent Medtronic a letter asserting that seven of Medtronic's implantable cardiac resynchronization devices infringe "at least one of" twelve claims of the '119 patent. JA30.

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[3] Respondent Boston Scientific Corporation is Guidant's corporate parent. Pet. App. 22a.

On October 23, 2007, another patent issued that MFV claimed was subject to the 1991 sublicense and 2006 LTA: U.S. Reissue Patent No. RE39,897 ("the '897 patent"), which contains 331 patent claims. About a month later, MFV's counsel sent Medtronic a further letter amending its earlier notice and asserting that the seven accused products infringe "at least one of" 29 claims of the '119 and '897 patents. JA32.

E. Proceedings In The District Court

In December 2007, Medtronic filed this suit. As contemplated in the LTA, it sought a declaration that the accused devices do not infringe any valid and enforceable claim of the '119 and '897 patents. JA45. In its Answer, MFV admitted that it was asserting that certain of Medtronic's implantable cardiac resynchronization devices infringe its patents. JA47. Over the course of the litigation, MFV twice changed the claims it asserted.[4] By the time of trial, MFV had added one claim of the '119 patent, dropped nine claims of the '897 patent, and substituted six others. Pet. App. 30a-31a (listing claims asserted at trial); *see* JA41-42, 48 (describing previous assertions).

The parties disagreed over the placement of the burden of proof, with MFV insisting that Medtronic, as the nominal plaintiff, bore the burden of proving that its products did *not* infringe the specified claims of the patents.[5] Apparently in reliance on this position, MFV declined to state the basis for its assertion that Medtronic's products meet each and every limitation of the asserted claims, as would be required in an affirmative patent infringement suit, *see, e.g.*, *Presidio Components, Inc.* v. *American Technical Ceramics Corp.*, 702 F.3d 1351, 1358 (Fed. Cir. 2012). It similarly failed to offer affirmative evidence establishing all of the elements of infringement. In his deposition, for example, MFV's proposed expert on infringement admitted that he had not mapped every limitation of the asserted patent claims onto features of Medtronic's accused devices, despite acknowledging that this is typically "what you do" in an infringement analysis. Pet. App. 45a-46a.

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[4] MFV also asserted a counterclaim arising out of a separate dispute between the parties. JA1 (Dkt. 114). That counterclaim was subsequently dismissed by stipulation. JA4 (Dkt. 268).

After a five-day bench trial, the district court ruled that Medtronic's status as a declaratory judgment plaintiff did not relieve MFV, as the patent holder "asserting infringement," of the usual burden to prove infringement by a preponderance of the evidence. Pet. App. 41a. The district court then concluded that MFV's expert testimony "lack[ed] sufficient foundation" under Federal Rule of Evidence 702. *Id.* 49a & n.12; *see also id.* 41a-44a (discussing Rule 702 and *Daubert* v. *Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993)). Without admissible expert testimony, MFV "failed to prove literal infringement by a preponderance of the evidence." *Id.* 49a. For similar reasons, the court also concluded that MFV failed to show infringement under the doctrine of equivalents. *Id.* 52a. The district court entered a declaratory judgment in Medtronic's favor under Federal Rule of Civil Procedure 54(b). JA3 (Dkt. 263).[6]

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[5] The "burden of proof" at issue in this case is the "burden of persuasion," which lies with "the party who must persuade the [trier of fact] in its favor to prevail." *Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 n.4 (2011). In other words, "if the evidence is evenly balanced" or if there is no evidence offered on a particular issue, then the allocation of the burden is determinative and the party bearing the burden loses. *Director, Office of Worker's Comp. Programs* v. *Greenwich Collieries*, 512 U.S. 267, 272 (1994). This burden is distinct from a "burden of production," which specifies "which party must come forward with evidence at various stages in the litigation." *Microsoft*, 131 S. Ct. at 2245 n.4.

F. Proceedings In The Court Of Appeals

The Federal Circuit reversed the district court's ruling on the burden of proof, vacated the judgment, and remanded for further proceedings. Pet. App. 14a, 18a.

The Federal Circuit recognized the "well settled" rule that a "patentee who files a complaint or counterclaim alleging patent infringement bears the burden of proving that infringement." Pet. App. 10a. It also acknowledged the "general proposition that mere role reversal in a declaratory judgment action does not shift the burden" of proof. *Id.* 11a. That is so, the court stated, because in most declaratory judgment actions brought by a party contesting the scope or validity of a patent, the patent holder counterclaims for damages for infringement. According to the court of appeals, such "a declaratory judgment action of invalidity with an infringement counterclaim is nothing more than an inverted infringement suit," and so the patentee retains the burden of proof on infringement. *Id.*

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[6] The '119 and '897 patents expired on January 23, 2009. Pet. App. 30a. Although Medtronic accordingly is no longer accruing additional potential liability for royalties, it continues to maintain an amount sufficient to cover the disputed royalty payments, with interest, as required by the LTA. JA27-28. In its 2012 Form 10-K filed with the Securities and Exchange Commission, Medtronic reported that the accumulated amount totaled $120 million. *See* Medtronic, Inc., Form 10-K at 117 (June 26, 2012), *available at* http://www.sec.gov/Archives/edgar/data/64670/000089710112001054/medtronic122599_10k.htm.

But the court believed that a different result is required in cases like this one and others brought under *MedImmune*, where there can be no counterclaim for infringement damages because the declaratory judgment plaintiff is a licensee in good standing: "In this case, as sanctioned by *MedImmune*, the continued existence of the license precludes the very infringement counterclaim that normally would impose the burden of proving infringement on the patentee." Pet. App. 12a. In such a situation, the court stated, the burden of proof rests with the party that initiated the litigation, and the licensee must prove that its products *do not* infringe the patent. *Id.* 11a-12a.

The Federal Circuit recognized that this case is in substance an inverted infringement action, acknowledging that "Medtronic's suit for declaratory judgment undoubtedly rests upon the infringement provisions laid out in [35 U.S.C.] § 271." Pet. App. 12a. But in the court's view, the fact that "the relief [Medtronic] seeks relates directly to its obligations under the license" required placing the burden of proof on Medtronic because "it is Medtronic and not MFV that is asking the court to disturb the status quo ante and to relieve it from a royalty obligation it believes it does not bear." *Id.* 12a-13a. In that context, the Federal Circuit ruled, courts should effectively presume that the accused products infringe unless proven otherwise. *Id.* 13a ("If neither party introduced any evidence regarding infringement or noninfringement there is no principled reason why Medtronic should receive the declaration of noninfringement it seeks.").

As the Federal Circuit summarized its holding, "when an infringement counterclaim by a patentee is foreclosed by the continued existence of a license, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion." Pet. App. 14a.[7]

SUMMARY OF ARGUMENT

I. The Declaratory Judgment Act is a purely procedural statute that neither enlarges the jurisdiction of the federal courts nor alters substantive rights. This Court has thus instructed that courts must determine matters of jurisdiction and substance in declaratory actions by referring to the equivalent coercive suit—that is, the suit in which the same issue would have been litigated if the declaratory judgment procedure did not exist.

The same rule governs the allocation of the burden of proof. The burden of persuasion in litigation is a matter of substance reflecting a legislative policy judgment in the governing substantive law. Accordingly, as with other matters of substance and jurisdiction, a court hearing a declaratory judgment action should assign the burden of proof based not on the nominal status of the parties in the declaratory suit, but rather on where the burden would lie in the corresponding coercive action. The overwhelming weight of authority supports this sensible rule, and this Court has held in other contexts that the burden of proof should not vary when parties can litigate the same dispute through two different but correlative procedures. The same logic applies here.

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[7] The Federal Circuit separately reversed the district court's claim construction of the '119 patent and stated that "Medtronic may press its invalidity contention based upon the correct claim construction" on remand. Pet. App. 18a. That ruling is correct and unworthy of this Court's review, as stated in Medtronic's brief in opposition to MFV's pending petition for certiorari (No. 12-1116).

A contrary rule would frustrate the purposes of the Declaratory Judgment Act. First, because the burden of proof is always important and often outcome-determinative, a rule automatically assigning the burden to declaratory judgment plaintiffs would penalize parties seeking declaratory relief and discourage the use of a mechanism that Congress sought to foster. Second, the Act's basic purpose is to provide a final, binding resolution to the parties' dispute—a result typically achieved through ordinary rules of issue preclusion. But if the nominal reversal of party status also shifted the burden of proof, giving preclusive effect to the result of a declaratory action would often be inconsistent with basic rules of preclusion. It is well settled that a losing party is not precluded from relitigating an issue if it bore the burden of proof in the first action but its opponent bears the burden in the second action. Accordingly, if a declaratory judgment plaintiff failed to carry its burden, it could claim the right to relitigate the very same issue in any future coercive action in which the prevailing declaratory judgment defendant would bear the burden. That would be wasteful and contrary to Congress's purpose in creating the declaratory judgment procedure.

II. The above principles establish that the assignment of the burden of proof in a suit seeking a declaratory judgment of noninfringement should track the patent laws' assignment of the burden in a coercive patent infringement suit. Well established substantive patent law places the burden of proving infringement on the patent holder who asserts it.

When a patent holder accuses another party of infringement and that party responds by filing a suit seeking a declaration of noninfringement, the declaratory action is simply an inverted infringement suit. Accordingly, as every court to consider the question had previously concluded, the burden of proof remains where the substantive patent law places it—with the patent holder. That is the only result consistent with the general rule governing the allocation of burdens of proof in declaratory actions.

There is no support for the Federal Circuit's creation of a special rule in *MedImmune*-type declaratory actions.

First, the court of appeals thought it significant that the presence of a license prevents the patent holder from bringing a coercive counterclaim for infringement damages. But the presence or absence of a counterclaim is irrelevant: The burden of proof lies with the patent holder in a typical declaratory action not because of the counterclaim, but rather because the declaratory judgment procedure preserves the substantive law's assignment of the burden.

Second, the court of appeals believed that the licensee should bear the burden in *MedImmune*-type suits because it is seeking to disturb the status quo and relitigate an issue that was "settled" by the license. But as this Court recognized, that argument has no force in cases like *MedImmune*, where the licensee has agreed to pay royalties only for products that actually infringe the licensed patent. And it is particularly unavailing in this case, where the parties' agreement expressly acknowledges the existence of a dispute over the validity and scope of MFV's patents and provides that MFV will not receive the disputed royalties unless and until it prevails in this suit. Moreover, although the Federal Circuit invoked general principles governing the allocation of burdens of proof, it overlooked the established principle that the burden should be assigned to the party asserting the affirmative of an issue—here, the patent holder—because of the difficulty of proving a negative proposition like *non*infringement.

Third, the Federal Circuit's decision frustrates important patent policies by discouraging licensees from bringing declaratory actions. Licensees are often the only parties with an economic incentive to challenge a patent's scope, and such suits benefit the public at large by narrowing overbroad patents and clarifying the line between the public domain and the patent holder's monopoly. The Federal Circuit's ruling that a licensee's challenge to a patent's scope comes at the price of shouldering the burden of proof unnecessarily discourages such salutary challenges, with no concomitant benefit to the public policies underlying either the Patent Act or the Declaratory Judgment Act.

ARGUMENT

I. THE NOMINAL REVERSAL OF TRADITIONAL PARTY STATUS IN A DECLARATORY JUDGMENT ACTION DOES NOT ALTER THE SUBSTANTIVE LAW'S ALLOCATION OF THE BURDEN OF PROOF

A. The Labeling Of Parties As Plaintiffs Or Defendants In A Declaratory Judgment Action Does Not Alter Substantive Legal Rules

1. The Declaratory Judgment Act authorizes potential defendants to obtain a definitive adjudication of their rights *before* taking action that could trigger liability. Indeed, "'the very purpose of the Declaratory Judgment Act [was] to ameliorate'" the "dilemma"

posed when a party is put "to the choice between abandoning his rights or risking" liability by proceeding with allegedly unlawful conduct. *MedImmune Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 129 (2007); *see id.* at 134. Applying this principle, *MedImmune* held that a patent licensee can seek a declaration of noninfringement even as it continues to pay royalties under protest; the licensee need not "take[] the final step of refusing to make royalty payments," thereby risking treble damages and attorney's fees. *Id.* at 128.

In enacting the Declaratory Judgment Act, Congress sought to "avoid[] the necessity" of forcing one threatened with liability "to act at one's peril" or else "abandon one's rights because of a fear of incurring damages." S. Rep. No. 73-1005, at 2 (1934). The value of the declaratory judgment procedure lies in its power to resolve disputes *before* "an injury has occurred," H.R. Rep. No. 73-1264, at 2 (1934), and "without requiring a destruction of the status quo and of the social and economic fabric," S. Rep. No. 73-1005, at 6, that comes with forcing the parties into a breach of legal obligations and the attendant litigation.

2. An action seeking a declaration of non-liability reverses the natural lineup of parties in a dispute. The traditional plaintiff, which in the absence of the Act would have enforced its rights in a coercive suit, becomes the declaratory judgment defendant, and the traditional defendant becomes the declaratory judgment plaintiff. But this Court and other federal courts have repeatedly made clear that this switch in nominal party status does not affect the substantive law governing the parties' dispute.

As this Court has explained, "the operation of the Declaratory Judgment Act is procedural only."

Aetna Life Ins. Co. v. *Haworth*, 300 U.S. 227, 240 (1937). Thus, while the Declaratory Judgment Act effected "substantial procedural reform," it left "substantive rights unchanged." *Beacon Theatres, Inc.* v. *Westover*, 359 U.S. 500, 508-509 (1959); *see also id.* at 514 (Stewart, J., dissenting) ("[T]he Declaratory Judgment Act did not 'expand' the substantive law."); *Skelly Oil Co.* v. *Phillips Petroleum Co.*, 339 U.S. 667, 674 (noting "the limited procedural purpose of the Declaratory Judgment Act"). Indeed, except for the absence of coercive relief, a suit seeking a declaration of non-liability involves "'the same court, the same jurisdiction, the same procedure, the same parties and the same question'" as the equivalent suit for damages or an injunction. S. Rep. No. 73-1005, at 3.

For most purposes, therefore, it is "immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed." *Maryland Cas. Co.* v. *Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Because the Declaratory Judgment Act is "procedural only," *Aetna*, 300 U.S. at 240, the reversal of party status it authorizes does not expand the jurisdiction of the courts or alter the content of substantive rights.

Courts determining matters of jurisdiction or substance in declaratory judgment actions must therefore look to the coercive action in which the same dispute would have arisen "'but for the availability of the declaratory judgment procedure.'" *Franchise Tax Bd. of Cal.* v. *Construction Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 16 (1983). Where the traditional arrangement of parties is reversed in a suit seeking a declaration of non-liability, this equivalent coercive action is the one the declaratory judgment *defendant* would have brought to enforce its asserted rights. *Id.* at 19.

This Court has considered the effect of the reversal of party status most frequently in the context of federal-question jurisdiction. Ordinarily, jurisdiction is determined under "the longstanding well-pleaded complaint rule," which provides that "a suit 'arises under' federal law 'only when the plaintiff's statement of his own cause of action shows that it is based upon [federal law].'" *Vaden* v. *Discover Bank*, 556 U.S. 49, 60 (2009) (alteration in original). Thus, a defendant that raises a federal defense to a state-law cause of action cannot establish federal jurisdiction merely by pleading that federal defense in its response to the complaint. *See id.* But because a declaratory judgment action reverses the normal party status of the litigants, when a potential defendant facing a state-law claim files a declaratory action, its federal defenses to anticipated liability ordinarily *will* appear on the face of its complaint seeking a declaration of non-liability.

This Court has recognized, however, that the well-pleaded complaint rule cannot be circumvented in that manner if the courts are to give effect to Congress's direction that the Declaratory Judgment Act did not enlarge the subject matter jurisdiction of the federal courts, *see Skelly Oil*, 339 U.S. at 671-672. Accordingly, a court applying the well-pleaded complaint rule in a declaratory action must ask whether, "if the [traditional plaintiff] brought a coercive action to enforce its rights, that suit would necessarily present a federal question." *Franchise Tax Bd.*, 463 U.S. at 19. In other words, "the well-pleaded complaint rule applies in actions brought under the Declaratory Judgment Act, but ... the inquiry must be inverted" and applied to "the potential coercive action that the defendant might bring against the declaratory judgment plaintiff."

15 *Moore's Federal Practice* § 103.44[1] (2013) (footnote omitted).

The same analysis applies in determining the scope of the Seventh Amendment right to trial by jury. The Declaratory Judgment Act, "while allowing prospective defendants to sue to establish their nonliability, specifically preserves the right to jury trial for both parties." *Beacon Theaters*, 359 U.S. at 504. Thus, whether parties to a declaratory judgment action have a jury right depends on whether such a right would exist if the declaratory judgment procedure were not available and the traditional plaintiff filed a coercive action raising the same issues. If the traditional plaintiff "would have been entitled to a jury trial in" that hypothetical coercive suit, it "cannot be deprived of that right merely because" the traditional defendant "took advantage of the availability of declaratory relief to sue ... first." *Id.*; *accord* 12 *Moore's Federal Practice* § 57.64 (2013); 9 Wright & Miller, *Federal Practice and Procedure* § 2313 (3d ed. 2008).

Finally, this Court has also emphasized the substantive equivalence of a declaratory action and the corresponding coercive suit in holding that declaratory judgment cases can satisfy Article III's case-or-controversy requirement. In a suit brought by an insurer seeking a declaration of non-liability, the Court explained that "[i]f the insured had brought suit to recover [damages under] the policies there would have been no question that the controversy was of a justiciable nature." *Aetna*, 300 U.S. at 243. It then concluded that the declaratory action brought by the insurer also satisfied Article III because "the character of the controversy and of the issue to be determined is essentially the same whether it is presented by the insured or by the insurer. ... It is the nature of the controversy, not the method of its presentation or the particular party who presents it, that is determinative." *Id.* at 244.

B. The Allocation Of The Burden Of Proof Is A Rule Of Substantive Law That Is Not Altered By The Declaratory Judgment Act

1. "[T]he assignment of the burden of proof is a rule of substantive law." *Director, Office of Worker's Comp. Programs* v. *Greenwich Collieries*, 512 U.S. 267, 271 (1994); *accord Raleigh* v. *Illinois Dep't of Revenue*, 530 U.S. 15, 20-21 (2000). The placement of the burden on a claim under any particular statute reflects the legislature's policy judgment as to how that statute should operate; it is therefore "a part of the very substance of [the] claim and cannot be considered a mere incident of a form of procedure." *Garrett* v. *Moore-McCormack Co.*, 317 U.S. 239, 249 (1942); *see also Raleigh*, 530 U.S. at 21 ("[T]he burden of proof is an essential element of the claim itself."); *American Dredging Co.* v. *Miller*, 510 U.S. 443, 454 (1994) (the burden of proof "bear[s] upon the substantive right to recover," upon which "actors rely in making decisions about primary conduct"). Allocation of the burden of proof is therefore no trivial matter: a party defending against a claim has a "*right* ... to be free from the burden" that "inhere[s]" in the substantive law. *Garrett*, 317 U.S. at 249 (emphasis added).

Because the allocation of the burden of proof is a question of substantive law, it cannot be altered by the Declaratory Judgment Act, which is "procedural only." *Aetna*, 300 U.S. at 240. Indeed, to allow the reversal of party status to shift the burden of proof would impermissibly transform the Declaratory Judgment Act from one creating a special litigation *procedure* into one that alters the governing *substantive law*.[8]

Instead, courts hearing declaratory judgment actions should allocate the burden of proof the same way they determine their jurisdiction and the presence or absence of a jury-trial right: By asking how the situation would unfold in the coercive action in which the same dispute would have arisen "'but for the availability of the declaratory judgment procedure.'" *Franchise Tax Bd.*, 463 U.S. at 16. This approach ensures that, just as the Declaratory Judgment Act does not expand the jurisdiction of the federal courts or alter the scope of the Seventh Amendment right, it also does not change the substantive law governing the parties' dispute.

2. Although this Court has never directly confronted the question of the burden of proof in the declaratory judgment context, it has rejected the notion that the burden of proof should turn on party status or other purely procedural matters where, as here, the parties could litigate the same dispute through two different procedures. For example, in *Alaska Department of Environmental Conservation* v. *EPA*, 540 U.S. 461 (2004), the EPA had the option of enforcing the

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[8] The principle that different procedures and remedies cannot alter the substantive burden of proof has long governed when parties pursue federal claims in state court. Although state courts may differ significantly from federal courts in the procedures and remedies that they make available, they may not alter the burden of proof on a federal claim, for doing so would impermissibly change the substance of federal law. *See Garrett*, 317 U.S. at 245. For similar reasons, state law governs the allocation of the burden in state-law causes of action litigated in federal court. *See, e.g.*, *Dick* v. *New York Life Ins. Co.*, 359 U.S. 437, 446 (1959); *Cities Serv. Oil Co.* v. *Dunlap*, 308 U.S. 208, 210-211 (1939).

Clean Air Act either by beginning a civil action as plaintiff or by issuing an order that could be challenged in a lawsuit naming the EPA as defendant. This Court noted that "Congress nowhere suggested that the allocation of proof burdens would differ depending upon which enforcement route EPA selected." *Id.* at 493. The Court therefore held that, regardless of whether the EPA was a plaintiff or a defendant, "the production and persuasion burdens ... and the underlying question a reviewing court resolves remain[] the same." *Id.* at 494.

The Court reached a similar conclusion in *F. Vitelli & Son* v. *United States*, 250 U.S. 355, 358 (1919), in which a customs collector directed "reliquidation" of certain imported merchandise on the assertion that the importer had fraudulently undervalued the merchandise and thus paid too little in customs duties. Although the importer could have "refused to pay the duty resulting from the reliquidation and awaited action taken against him by the United States to enforce it," the importer instead paid the duties and filed a protest. *Id.* This Court considered whether, by choosing to file an affirmative protest, the importer had "assumed the burden of proof"—a burden he would not have borne had he merely defended against a later enforcement action by asserting the impropriety of the reliquidation. *Id.* The Court rejected that proposition, holding that the importer could not be forced to bear the burden of proof merely because he sought "resort to the remedy appropriate for" the wrong rather than waiting for a coercive enforcement action by the government. *Id.* at 359.

3. As in *Alaska Department of Environmental Conservation* and *Vitelli*, the fact that the declaratory judgment procedure causes a reversal in party status

should not change the substantive law's allocation of the burden of proof. Thus, many lower courts have recognized—in cases arising under both federal and state law—that there is "no reason to deviate from" normal "burden of proof principles simply because [an] action was brought by the [traditional defendant] under the federal Declaratory Judgment Act." *American Eagle Ins. Co.* v. *Thompson*, 85 F.3d 327, 331-332 (8th Cir. 1996). Indeed, as the Second Circuit recognized long ago, "[i]t would seem rather anomalous that so important a matter [as the burden of proof] should depend on the chance of who first sues." *Preferred Accident Ins. Co.* v. *Grasso*, 186 F.2d 987, 991 (2d Cir. 1951) (Clark, J.).[9] And Professor Borchard similarly maintained that the reversal of parties in an action for a declaration of non-liability did not shift the burden of proof. *See* Borchard, *Declaratory Judgments* 404-409 (2d ed. 1941); *see also* 12 *Moore's Federal Practice* § 57.62.

Even the Federal Circuit endorsed "the general proposition that mere role reversal in a declaratory judgment action does not shift the burden" (Pet. App. 11a), and acknowledged that in insurance cases—where the issue often arises—"courts generally place the burden on the party seeking recovery under a policy ... even when the insured is the declaratory judgment defendant" (*id.* 13a). But the court then stated that "the burden can shift to the declaratory judgment plaintiff where the insured is not seeking affirmative relief." *Id.* This statement finds no support in the sole authority on which the Federal Circuit relied, *Reliance Life Ins. Co.* v. *Burgess*, 112 F.2d 234, 237 (8th Cir. 1940). As the Eighth Circuit later explained, the issue in *Burgess* was "an affirmative defense" on which the insurer would have borne the burden even in a coercive suit brought by the insured. *American Eagle*, 85 F.3d at 331. Accordingly, *Burgess* has long been understood—including within the Eighth Circuit—as an application of the settled proposition that the burden of proof in a declaratory judgment action rests with the same party that would bear it in an equivalent coercive suit. *See id.* at 331-332; *Fireman's Fund Ins. Co.* v. *Videfreeze Corp.*, 540 F.2d 1171, 1175-1176 (3d Cir. 1976); *Preferred Accident Ins.*, 186 F.2d at 991; *Declaratory Judgments* 407-408.[10]

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[9] *See also, e.g.*, *Adelson* v. *Hananel*, 652 F.3d 75, 84-85 (1st Cir. 2011); *James River Ins. Co.* v. *Kemper Cas. Ins. Co.*, 585 F.3d 382, 385 (7th Cir. 2009) (Posner, J.); *Graoch Assocs. #33, L.P.* v. *Louisville/Jefferson County Metro Human Relations Comm'n*, 508 F.3d 366, 371-379 & n.2 (6th Cir. 2007); *Starter Corp.* v. *Converse, Inc.*, 170 F.3d 286, 291 (2d Cir. 1999); *Fireman's Fund Ins. Co.* v. *Videfreeze Corp.*, 540 F.2d 1171, 1176 (3d Cir. 1976); *Board of Regents of Univ. of Neb.* v. *Dawes*, 522 F.2d 380, 383 n.9 (8th Cir. 1975).

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[10] It is not even clear that *Burgess* assigned the burden of proof on substantive matters to the insurer at all. The Eighth Circuit held that the district court had correctly placed the burden of proof on the plaintiff insurance company at the outset of the litigation, because at that point the defendants "denied that a justiciable controversy existed" and did not assert any right to recover under the insurance policies. *Burgess*, 112 F.2d at 237-238. Thus, the Eighth Circuit may have made only the uncontroversial ruling that a declaratory judgment plaintiff bears the burden of proof with respect to the existence of a justiciable controversy. *See* 12 *Moore's Federal Practice* § 57.62[1]. But *Burgess* did not hold that the insurer bore the burden on the merits of the dispute once the declaratory judgment defendants changed their position and contested the insurer's claim of non-liability. In fact, the court appeared to decline to pass on that question. *See Burgess*, 112 F.2d at 238 ("[W]e do not deem it essential to pursue the question further.").

The Federal Circuit also invoked *Schaffer ex rel. Schaffer* v. *Weast*, 546 U.S. 49, 56 (2005), which stated that "the ordinary default rule" places the burden of proof on "'the plaintiff who generally seeks to change the present state of affairs.'" *See* Pet. App. 9a-10a. But that "default rule" only helps the courts determine where the relevant *substantive law* places the burden. *See Schaffer*, 546 U.S. at 56 ("[In] determining the burden of proof under a statutory cause of action, the touchstone of our inquiry is, of course, the statute."). Indeed, *Schaffer* and the precedents on which it relied involved the allocation of the burden in *coercive* actions, not declaratory judgments. *See id.* at 56-61.[11] *Schaffer* is thus entirely consistent with the principle that the burden of proof in a declaratory action remains with the party that would bear it in an equivalent coercive suit.

Aside from *Burgess*, a minority of courts have assumed or concluded that the insurer bears the burden of proof in a suit seeking a declaration of non-liability even though the insured would bear it in a traditional coercive action raising the same issue. *See, e.g.*, *Maryland Cas. Co.* v. *Baldwin*, 357 F.2d 338, 339 (4th Cir. 1966) (per curiam); *Metropolitan Cas. Ins. Co. of N.Y.* v. *Miller*, 188 F.2d 702, 704 (7th Cir. 1951); *see also* 10B Wright et al., *Federal Practice and Procedure* § 2770 (3d ed. 1998) (recognizing division in authority). But many of these cases contain little or no analysis of the issue, and others rest on the conclusion that the insurer essentially waived the issue by voluntarily assuming the burden of proof at trial. *See, e.g.*, *Liberty Mut. Ins. Co.* v. *Sweeney*, 216 F.2d 209, 211 (3d Cir. 1954).

[11] Two of the cases cited in *Schaffer* involved suits seeking both declaratory and coercive relief, but neither discussed the allocation of the burden of proof on the merits of a declaratory judgment claim. *See Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (standing); *Doran* v. *Salem Inn, Inc.*, 422 U.S. 922, 931 (1975) (preliminary injunction).

C. A Contrary Rule Would Frustrate The Purposes Of The Declaratory Judgment Act

If the reversal of traditional party status in a declaratory action altered the otherwise-applicable burden of proof, the Declaratory Judgment Act would be undermined in at least two important ways.

1. Shifting the burden of proof would undermine the Act's utility in avoiding uncertainty and disruption

The Declaratory Judgment Act was intended to allow a party threatened with liability to secure a judicial determination of its rights without risking damages by engaging in the challenged conduct and prompting a coercive suit. *MedImmune*, 549 U.S. at 128-129, 133-134. But if parties seeking declarations of non-liability were forced to assume the burden of proof that would otherwise belong to their opponents, the utility of this procedure would be greatly diminished. Parties facing the possibility of liability in a coercive suit would be much less likely to make use of the declaratory judgment remedy if the cost of doing so were a forced assumption of the burden of proof, and with it many of the risks of litigation.

As this Court has recognized, "[w]here the burden of proof lies on a given issue is ... rarely without consequence and frequently may be dispositive to the outcome of the litigation." *Lavine* v. *Milne*, 424 U.S. 577, 585 (1976); *see also Raleigh*, 530 U.S. at 20-21 (noting the "importance" of the allocation of the burden "to the outcome of cases"). A potential defendant to a coercive suit would surely hesitate to invoke the declaratory judgment procedure if doing so significantly increased the likelihood that it would lose the litigation. A rule that shifted the burden of proof to the declaratory judgment plaintiff would thus recreate a version of the same dilemma that the Act was intended to eliminate: A party facing an assertion of liability could not obtain a judicial determination of its rights unless it was willing to incur potential liability in a coercive suit or to assume the burden of proof in a declaratory judgment action—a burden that could well prove "dispositive to the outcome," *Lavine*, 424 U.S. at 585.

Shifting the burden of proof would therefore undermine the Act's goal of encouraging the use of a procedure that Congress viewed as offering substantial benefits to the parties, the courts, and the public. *See* S. Rep. No. 73-1005, at 6 (the Act allows disputes to be resolved "without requiring a destruction of the status quo and of the social and economic fabric"); *id.* at 3 (the Act avoids the "social and economic waste and destruction" caused by coercive suits after damages have been incurred). Furthermore, because the declaratory judgment plaintiff has been granted "the right to an adjudication of the claim without waiting for [its opponent] to institute legal proceedings, it ought not to suffer and to have to pay a price by exercising its right." *Travelers Ins. Co.* v. *Greenough*, 190 A. 129, 130 (N.H. 1937); *see Declaratory Judgments—Burden of Proof—Action by Insurance Company for Declaration as to Coverage of Policy*, 37 Colum. L. Rev. 1006, 1008 (1937) (discussing *Greenough*) (shifting the burden to a party seeking a declaration of non-liability "would penalize the use of an instrument which has valuable potentialities").[12]

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[12] Although based on New Hampshire law, *Greenough* has been treated as a persuasive articulation of general burden of proof principles as they apply to declaratory judgment actions,

2. Shifting the burden of proof would undermine the finality of declaratory judgments

A declaratory judgment would serve little purpose if the losing party could simply relitigate the same issues in a subsequent suit. Under the Federal Circuit's rule, however, it is doubtful that a victory by a declaratory judgment defendant would definitively resolve anything: The unsuccessful declaratory judgment plaintiff could insist that it had the right to relitigate the very same issue in any future coercive action between the parties, because the burden of proof in such litigation would shift to its opponent. This possibility would drain the Act of much of its usefulness.

The Declaratory Judgment Act expressly provides that a declaratory judgment "shall have the force and effect of a final judgment," 28 U.S.C. § 2201(a), and authorizes a prevailing party to seek "[f]urther necessary or proper relief ... against any adverse party whose rights have been determined by such judgment," *id.* § 2202. These provisions ensure that a declaratory judgment serves as a "definitive determination of the legal rights of the parties." *Aetna*, 300 U.S. at 241. This binding character is what distinguishes declaratory judgments from "the mere advisory opinions prohibited by Article III." 18A Wright et al., *Federal Practice and Procedure* § 4446 (2d ed. 2002).

The determinations reflected in a declaratory judgment are made binding by the doctrine of issue preclusion, which "bars 'successive litigation of an issue of fact or law actually litigated and resolved in a valid

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including under federal law. *See, e.g.*, *Fireman's Fund*, 540 F.2d at 1175; *Declaratory Judgments* 405-406.

court determination essential to [a] prior judgment.'" *Taylor* v. *Sturgell*, 553 U.S. 880, 892 (2008). As with any other final judgment, "a judgment in a declaratory action should (indeed, must) be given issue preclusive effect if the requisites for according that effect are met." Shapiro, *Civil Procedure: Preclusion in Civil Actions* 63 (2001); *see* 18A *Federal Practice and Procedure* § 4446 ("[m]atters actually litigated by the parties and determined by a declaratory judgment are ... precluded from further litigation" under ordinary principles of issue preclusion); *see also Restatement (Second) of Judgments* § 33 (1982).[13]

Issue preclusion does not apply, however, when the burden of persuasion in the subsequent action has "shifted" from the party against whom preclusion is sought "to his adversary." *Restatement (Second) of Judgments* § 28(4). Instead, it is "well established" that the "failure of one party to carry the burden of persuasion on an issue should not establish the issue in favor of an adversary who otherwise would have the burden of persuasion on that issue in later litigation." 18A *Federal Practice and Procedure* § 4422. Courts and commentators have therefore uniformly recognized that a party should not be precluded from defending itself in a lawsuit on a particular issue merely because it failed to carry an affirmative burden of proof on that issue in an earlier action. *See Restatement (Second) of Judgments* § 28 cmt. f.[14]

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[13] In general, the preclusive effect of a declaratory judgment is defined exclusively by *issue* preclusion, not claim preclusion, because "traditional doctrine has refused to apply claim preclusion to an action for declaratory relief alone." 18A *Federal Practice and Procedure* § 4446; *see also Andrew Robinson Int'l, Inc.* v. *Hartford Fire Ins. Co.*, 547 F.3d 48, 56 (1st Cir. 2008) (collecting cases).

The Federal Circuit's approach creates an irreconcilable conflict between these settled rules of preclusion and the principle that a declaratory judgment definitively resolves the matters declared. Under the Federal Circuit's ruling, if a declaratory judgment plaintiff lost its case because it failed to carry its burden of proof, one of two results would obtain, neither of which is satisfactory. If the declaratory judgment were issue preclusive in a later coercive suit (following the general rule that declaratory judgments are issue preclusive), then the declaratory judgment plaintiff would be barred from contesting an issue that it had never litigated under the applicable burden of proof—and its opponent would be unfairly allowed to obtain coercive relief without carrying the burden such relief ordinarily requires. On the other hand, if the declaratory judgment were *not* preclusive (following the exception to preclusion for burden shifting described above), then the declaratory judgment action would have failed to accomplish anything useful, as the parties would not have obtained a resolution of their rights and responsibilities.

The only way to ensure that a declaratory judgment action provides a definitive resolution of the parties' dispute in a manner consistent with the ordinary rules of issue preclusion is to preserve the same allocation of the burden of proof as would apply in an equivalent coercive action. As the balance of this brief explains, that means assigning the burden of proving infringement to the patentee, contrary to the Federal Circuit's decision in this case.

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[14] *See also, e.g., B & B Hardware, Inc.* v. *Hargis Indus., Inc.*, 716 F.3d 1020, 1026 (8th Cir. 2013); *McHan* v. *Commissioner*, 558 F.3d 326, 331 (4th Cir. 2009); *Kosinski* v. *Commissioner*, 541 F.3d 671, 678-679 (6th Cir. 2008); *Freeman United Coal Mining Co.* v. *Office of Workers' Comp. Program*, 20 F.3d 289, 294 (7th Cir. 1994); *Steelmet, Inc.* v. *Caribe Towing Corp.*, 747 F.2d 689, 693-694 (11th Cir. 1984); *cf. Grogan* v. *Garner*, 498 U.S. 279, 284-285 (1991) (citing *Restatement* § 28(4) with approval).

II. SUBSTANTIVE PATENT LAW ASSIGNS THE BURDEN OF PROVING INFRINGEMENT TO THE PATENTEE, AND THAT BURDEN DOES NOT SHIFT WHEN A PATENT LICENSEE SEEKS A DECLARATORY JUDGMENT OF NONINFRINGEMENT

Until the court of appeals' decision in this case, the courts had consistently ruled that the patentee, not the accused infringer, bears the burden of proving patent infringement. That rule has long been applied in both traditional infringement suits and in actions seeking declarations of noninfringement. The court of appeals' deviation from this rule lacks any persuasive justification and severely diminishes the value of the declaratory judgment remedy approved in *MedImmune*.

A. Federal Patent Law Places The Burden Of Proving Infringement On The Patent Holder

In a traditional coercive suit for patent infringement, patent law assigns the burden of proving infringement to the patent holder. *See, e.g.*, *Railroad Co.* v. *Mellon*, 104 U.S. 112, 119 (1881) ("Infringement must ... be shown by satisfactory proof; it cannot be presumed."); *Cammeyer* v. *Newton*, 94 U.S. 225, 231 (1877) ("Infringement is alleged by the complainants, and the burden is upon them to prove the allegation, as it imputes a wrongful act to the respondents."); *Agawam Co.* v. *Jordan*, 74 U.S. (7 Wall.) 583, 609 (1869) ("Infringement is an affirmative allegation made by the complainant, and the burden of proving it is upon him, unless it is admitted in the answer."). The Federal Circuit acknowledged this "well settled" rule (Pet. App. 10a), and, until the decision below, had consistently applied it as "axiomatic," *Ultra-Tex Surfaces, Inc.* v. *Hill Bros. Chem. Co.*, 204 F.3d 1360, 1364 (Fed. Cir. 2000).

It is equally well established that the burden of proving infringement "never shifts" during the course of litigation. *Imhaeuser* v. *Buerk*, 101 U.S. 647, 662 (1880); *see Technology Licensing Corp.* v. *Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008); *see also* 5B *Chisum on Patents* § 18.06 (2007) ("A patent owner bears the burden of proof by a preponderance of the evidence on fact issues relating to infringement[, although] [t]he burden of production of evidence may shift to the accused infringer on some issues[.]").

There is thus no question that, if the dispute in this case had come before the courts in a traditional coercive action, MFV would have borne the burden of proving infringement.

B. A Suit Seeking A Declaration Of Noninfringement Is Simply An Inverted Infringement Action And Does Not Shift The Burden To The Accused Infringer

In an action for a declaration of noninfringement, the declaratory judgment plaintiff places before the district court the very same controversy—*i.e.*, whether its products infringe the patents, as the patentee asserts—that would have been presented in a coercive action for patent infringement brought by the patentee. *See* 8 *Chisum on Patents* § 21.02[1][d][i] (2011) ("[A] suit by a declaratory plaintiff against a patent owner seeking a declaratory judgment that the plaintiff's products or process do not infringe a patent's claims … is essentially one for patent infringement with the parties reversed."). Therefore, consistent with the established rule for allocating the burden of proof in declaratory judgment actions, the nominal reversal of party status does not shift the burden of proof from the patent holder to the accused infringer. *See supra* Part I.

Every court that addressed the question before the court of appeals' decision in this case concluded that "[t]he burden of proof in a declaratory judgment action involving patent infringement is on the defendant owner of the patents at issue … just as if he were the plaintiff suing for infringement of those patents." *Deere & Co.* v. *Sperry Rand Corp.*, 322 F. Supp. 397, 398 (E.D. Cal. 1970), *aff'd*, 513 F.2d 1131 (9th Cir. 1975).[15] District courts have reached the same conclusion even where the declaratory judgment defendant did not counterclaim for infringement.[16] Indeed, Medtronic is unaware of *any* prior decision in which a court has charged an accused infringer with the burden of *disproving* patent infringement or claim coverage. The Federal Circuit certainly did not cite any such decisions.

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[15] *See also, e.g.*, *Uniroyal, Inc.* v. *Rudkin-Wiley Corp.*, 837 F.2d 1044, 1054 (Fed. Cir. 1988); *United Sweetener USA, Inc.* v. *Nutrasweet Co.*, 760 F. Supp. 400, 417 (D. Del. 1991); *Advanced Transformer Co.* v. *Levinson*, 1986 WL 84365, at *25 (N.D. Ill. June 17, 1986), *rev'd in part on other grounds*, 837 F.2d 1081 (Fed. Cir. 1988); *Philip A. Hunt Co.* v. *Mallinckrodt Chem. Works*, 72 F. Supp. 865, 873-874 (E.D.N.Y. 1947), *aff'd*, 177 F.2d 583 (2d Cir. 1949); *cf. Vivid Techs., Inc.* v. *American Sci. & Eng'g, Inc.*, 200 F.3d 795, 802 (Fed. Cir. 1999) ("'[A]ny role reversal occasioned by declaratory relief should not shift the burden of proof from the manner in which it would be assigned in a coercive infringement suit.'"); 12 *Moore's Federal Practice* § 57.62[2][d] (same).

[16] *See, e.g.*, *Zenith Labs., Inc.* v. *Bristol-Myers Squibb Co.*, 1992 WL 171910, at *1, *25 (D.N.J. July 21, 1992); *United Sweetener*, 760 F. Supp. at 408, 417; *see also Larami Corp.* v. *Amron*, 1994 WL 369251, at *8 (S.D.N.Y. July 13, 1994) (placing burden of proof on defendant trademark owner where "the defendant is the one making claims of infringement"); *see also MedImmune, Inc.* v. *Centocor, Inc.*, 271 F. Supp. 2d 762, 769-770 (D. Md. 2003) ("[T]he

Nor does the Federal Circuit's rule find any support in the patent laws. To the contrary, where Congress *has* intended to shift litigation burdens regarding infringement, it has done so expressly, as 35 U.S.C. § 295 does in a very specific context:

> In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, *if the court finds*—
>
> > (1) that a substantial likelihood exists that the product was made by the patented process, and
> >
> > (2) that the [patent holder] has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine,
>
> the product *shall be presumed to have been so made*[.]

(Emphases added.) Through § 295, Congress imposed a "rebuttable presumption" of infringement that shifts the burden of production in certain "carefully defined circumstances." S. Rep. No. 100-83, at 57 (1987). And even in that situation, Congress's addition of § 295 still did not relieve the patentee of the ultimate burden of

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patent holder retains the burden of proof despite being the nominal defendant.").

persuasion regarding infringement. *See id.* at 57-58; H.R. Rep. No. 100-60, at 16-17 (1987).

C. The Federal Circuit's New Exception For *MedImmune*-Type Cases Is Unjustified

There is no sound basis for the Federal Circuit's deviation from the usual allocation of the burden of proof in *MedImmune*-type declaratory judgment cases.

1. The presence or absence of an infringement counterclaim is immaterial

The Federal Circuit stated that the allocation of the burden of proof in an action for a declaration of noninfringement depends on the patentee's ability to assert a coercive counterclaim for infringement. Pet. App. 12a ("In this case, as sanctioned by *MedImmune*, the continued existence of the license precludes the very infringement counterclaim that normally would impose the burden of proving infringement on the patentee."). The court of appeals misunderstood the reason why the patentee retains the burden of proving infringement in a typical declaratory judgment action. It is *not* the presence of a counterclaim; indeed, the court cited no authority suggesting that the allocation of the burden of proof on a party's declaratory judgment claim (or any claim) should vary depending on whether its *opponent* files a counterclaim. Rather, the reason why the burden of proof in a declaratory judgment action is the same as in a mirror-image coercive action is that the declaratory judgment device is purely procedural and does not change substantive law. *See supra* Part I. Nor is there any basis for requiring a declaratory judgment plaintiff to bear the burden of proof, subject to being *relieved* of that obligation if the defendant counterclaims. Neither the Patent Act nor the Declaratory Judgment Act suggests any support for such a scheme.

The Federal Circuit also appeared to assume that the only possible claim or counterclaim a patent holder could bring was a coercive claim for damages or an injunction. *See* Pet. App. 14a (describing the present case as one in which "an infringement counterclaim by a patentee is foreclosed" by the license). But a patent holder—even one who is a licensor—may also bring a claim or counterclaim for a *declaratory judgment* of infringement or claim coverage, even where no actual infringement has yet occurred. *See, e.g.*, *Lang* v. *Pacific Marine & Supply Co.*, 895 F.2d 761, 763 (Fed. Cir. 1990) ("[W]e see no reason why a patentee should be unable to seek a declaration of infringement against a future infringer when a future infringer is able to maintain a declaratory judgment action for noninfringement under the same circumstances."); *see also* 12 *Moore's Federal Practice* § 57.22[8][c][ii]. Where both parties seek declaratory judgments, the labels of "claim" and "counterclaim" are merely byproducts of the order of filing. But there is no reason why the burden of proof should depend on the order of filing or whether the patent holder chooses to assert a declaratory judgment counterclaim. *See Fireman's Fund*, 540 F.2d at 1176.

2. The Federal Circuit's concerns about *MedImmune*-type litigation do not justify its deviation from the standard allocation of the burden of proof

The Federal Circuit also relied on additional considerations that it perceived to arise in the particular context of *MedImmune*-type litigation. But these points provide no support for its holding.

a. The Federal Circuit suggested that the licensee in a *MedImmune*-type suit should bear the burden because it is attempting to disturb the status quo by seeking "to be relieved from liability under the license by having a court declare the products in question noninfringing." Pet. App. 14a. In the Federal Circuit's view, "[a] contrary result would allow licensees to use *MedImmune*'s shield as a sword—haling licensors into court and forcing them to assert and prove what had already been resolved by license." *Id.*

That reasoning cannot be reconciled with *MedImmune* itself, where this Court explained that the controversy in this type of declaratory judgment action begins—as this one did—when the patentee/licensor claims a monopoly under the patent laws and implicitly or explicitly threatens to sue for damages or an injunction "if royalties are not forthcoming." 549 U.S. at 128. When the accused infringer responds by paying the demanded royalties, those payments are "coerced by threatened enforcement action"—*i.e.*, the prospect of a coercive suit by the patent holder. *Id.* at 130. And when the licensee seeks a declaration of non-liability without breaching the license, it is doing precisely what Congress allowed: pursuing a determination of disputed rights without risking liability. *See id.* at 128-129, 133-134. Moreover, this Court expressly rejected the suggestion that such a suit seeks to relitigate "what has already been resolved by license" (Pet. App. 14a); such an argument "ha[s] no force with regard to [a licensee's] claim that the agreement does not call for royalties because their product does not infringe the patent." 549 U.S. at 135.[17]

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[17] Under the MedImmune-Genentech license agreement, MedImmune was required to pay royalties only to the extent that

The Federal Circuit's mistake in this case is essentially the same as its mistake in *MedImmune*. As in *MedImmune*, the agreements at issue did not purport to "resolve[]" the parties' dispute by license (Pet. App. 14a); rather, the parties recognized from the beginning that Medtronic disputed the validity and scope of MFV's patents. JA19-20. The LTA thus sets forth not a *settlement* of the parties' dispute, but a framework for resolving it through *litigation*, namely a declaratory judgment action. JA24-28. In the meantime, Medtronic is not obligated to make the disputed royalty payments to MFV, but only to maintain the disputed amount and to certify to MFV that the funds are available. JA27-28. And the LTA specifically provides that MFV's right to payment of the disputed royalties will arise—if at all—*only when* it prevails in the declaratory judgment action. *See* JA28 (requiring Medtronic to distribute the disputed royalties "in a manner consistent with the decision in the DJ Action"). MFV thus is not a passive participant that merely seeks "to be discharged from the suit" (Pet. App. 12a); to the contrary, it started the controversy by asserting its right to royalties, an assertion that Medtronic denies, and MFV needs a judicial determination of infringement in order to have a right to payment of such royalties. *See* JA28 (MFV will have a right to payment based on patents "that Medtronic's products *were held to infringe*" (emphasis added)).

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its products would "'infringe one or more claims of either or both of [the covered patents,] which have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken.'" *MedImmune*, 549 U.S. at 121 (alteration in original) (quoting license agreement). MedImmune thus had no obligation to pay royalties if the patents were not infringed; the same is true of Medtronic.

The Federal Circuit thus erred in assuming that the parties' agreements established a "status quo" that Medtronic's suit seeks to "disturb." Pet. App. 13a. The very premise of the agreements was that there was an active, unsettled dispute between the parties, and the basis for that dispute was (and continues to be) MFV's assertion of a patent monopoly that it claims covers Medtronic's cardiac resynchronization products. It is entirely appropriate to require MFV to prove that claim, just as it would have to do if the same dispute were brought before the courts in an infringement action.[18]

Contrary to the Federal Circuit's expressed concern, moreover, there is little danger that a declaratory action will be used to "hal[e] licensors into court" unexpectedly. Pet. App. 14a. Declaratory judgment jurisdiction does not exist unless there is a "'substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *MedImmune*, 549 U.S. at 127. In the patent context, such a concrete dispute typically arises when the patentee asserts infringement and claims a right to royalties—as MFV did by directing its litigation counsel to send Medtronic two letters doing just that. JA30-33; *see, e.g.*, *Association for Molecular Pathology* v. *PTO*, 689 F.3d 1303, 1319-1320 (Fed. Cir. 2012), *rev'd in part on other grounds*, 133 S. Ct. 2107 (2013). There is thus no reason to believe that patentees will be caught unaware by declaratory judgment actions presenting true cases or controversies. If a patentee genuinely has no intention of pursuing any rights against the licensee, then it should be able to secure dismissal of the licensee's declaratory judgment suit. *See Organic Seed Growers & Trade Ass'n* v. *Monsanto Co.*, __ F.3d __, 2013 WL 2460949, at *3-4 (Fed. Cir. June 10, 2013); *cf. Adenta GmbH* v. *OrthoArm, Inc.*, 501 F.3d 1364, 1370 (Fed. Cir. 2007) (finding jurisdiction only after concluding that the patentee "indicated its intent to assert its rights under the … patent"). But if the patent holder does assert infringement (as MFV did here), there is no unfairness in requiring that it prove the assertion in court.

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[18] The Federal Circuit appeared to be concerned about the very different situation in which the patent holder and the licensee *resolve* an infringement claim by contracting for an agreed payment or stream of payments. Under those circumstances, the question of infringement might well be moot, as the payment would be based on the contract and would not vary depending on whether any product actually infringed the patent. But the concerns raised in such a situation do not arise in cases like *MedImmune* or this one, where the licensee's royalty obligation depends on a finding of infringement and the licensee challenges the scope of the patent from the outset.

b. The Federal Circuit's approach to *MedImmune*-type actions also ignores this Court's repeated admonitions about the difficulty of proving a negative. *See, e.g.*, *Vieth* v. *Jubelirer*, 541 U.S. 267, 311 (2004) (Kennedy, J., concurring in the judgment); *NLRB* v. *Kentucky River Cmty. Care, Inc.*, 532 U.S. 706, 711 (2001); *Elkins* v. *United States*, 364 U.S. 206, 218 (1960); *Piedmont & Arlington Life Ins. Co.* v. *Ewing*, 92 U.S. 377, 378-379 (1876).[19] Precisely because of the difficulty inherent in proving a negative, it has long been settled that the burden of proof should generally be assigned to "the party holding the affirmative of the issue." *Arthur* v. *Unkart*, 96 U.S. 118, 122 (1878); *see also Maxwell Land-Grant Co.* v. *Dawson*, 151 U.S. 586, 604 (1894). In this context, the party with the "affirmative" of the infringement issue is unquestionably the patent holder asserting infringement.

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[19] *See also Taylor* v. *Commissioner*, 70 F.2d 619, 621 (2d Cir. 1934) (Hand, J.) (declining to "invert the ordinary rules of procedure by imposing a burden of establishing a negative upon the obligor"), *aff'd*, 293 U.S. 507 (1935); *see also generally United States* v. *Ollie*, 442 F.3d 1135, 1143 (8th Cir. 2006) (observing that "the law generally frowns on requiring a party to prove a negative"); *Cole* v. *Stevenson*, 620 F.2d 1055, 1065 (4th Cir. 1980) (noting the "judicial disinclination to compel a party to prove a negative").

Moreover, proving *non*infringement of a patent is particularly difficult, not least because patents regularly contain dozens (even hundreds) of claims, infringement of any one of which triggers liability. *See, e.g.*, *Bio-Technology Gen. Corp.* v. *Genentech, Inc.*, 80 F.3d 1553, 1562 n.8 (Fed. Cir. 1996) ("Infringement of one valid and enforceable patent claim is all that is required for liability to arise."). Indeed, the two patents at issue here comprised more than 300 claims. While the parties' agreement limited MFV to asserting 30 claims (JA23-24, 26-27), other patentees are not so confined, and even MFV could (and did) substitute asserted claims over the course of the case. *See* Pet. App. 30a-31a (listing claims asserted at trial); JA41-42, 48 (describing previous assertions).

The Federal Circuit's rule places infringers in the particularly difficult position of disproving infringement under any possible theory, including theories under the doctrine of equivalents, which often involve assertions that cannot be predicted on the face of the patent and must instead be developed through expert testimony in litigation. *See, e.g.*, *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 37 (1997) (equivalents need not be disclosed in a patent in order to infringe the patent's claims); *AquaTex Indus., Inc.* v. *Techniche Solutions*, 479 F.3d 1320, 1329 (Fed. Cir. 2007) ("[T]he difficulties and complexities of the doctrine [of equivalents] require that evidence be presented ... through the particularized testimony of a person of ordinary skill in the art, typically a qualified expert."). Practicality and efficiency favor requiring the patentee to raise and articulate such infringement theories, rather than requiring the accused infringer to anticipate and refute them.

3. The Federal Circuit's rule frustrates important patent policies by undermining the declaratory judgment procedure recognized in *MedImmune*

The patent laws reflect "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969). This Court has thus adopted a "consistent view ... that the holder of a patent should not be insulated from the assertion of defenses and thus allowed to exact royalties for the use of an idea that is not in fact patentable *or that is beyond the scope of the patent monopoly granted.*" *Blonder-Tongue Labs., Inc.* v. *University of Ill. Found.*, 402 U.S. 313, 349-350 (1971) (emphasis added); *see also, e.g., FTC* v. *Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013) ("[E]ven a valid patent confers no right to exclude products or processes that do not actually infringe.").[20]

In *Lear*, this Court recognized that "[l]icensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery," and warned that "[i]f they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification." 395 U.S. at 670. The same logic applies to litigation regarding the *scope* of a patent, where licensees are often the only parties with sufficient incentive to litigate a patentee's assertions as to the breadth of its monopoly. As this Court has repeatedly emphasized, "'[t]he limits of a patent must be known.'" *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) (alteration in original). "Otherwise, a 'zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field,' and '[t]he public [would] be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights.'" *Id.* (citation omitted; alterations in original).

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[20] These principles underlie the settled rule that "[i]nfringement ... cannot be presumed." *Railroad Co.*, 104 U.S. at 119. Such a presumption would favor a monopoly over products or processes that could otherwise be marketed freely.

MedImmune recognized that these public policy interests are furthered by allowing a patent licensee to challenge the validity and scope of the licensed patent without "risk[ing] treble damages" by breaching the license and triggering an infringement suit. 549 U.S. at 134. But the Federal Circuit's decision here, if allowed to stand, would permit a licensee to pursue this course only at the price of shouldering a burden of proof that would otherwise lie with the patent holder—a shift that may well prove "dispositive," *Lavine*, 424 U.S. at 585.

Nothing in *MedImmune* suggests that a licensee must pay such a price to bring a declaratory judgment action, and the Federal Circuit's rule would improperly discourage the filing of *MedImmune*-type suits. That discouragement would harm not only licensees, but also the public, for unchallenged and overbroad patent claims both stall innovation and lead to higher prices. *See Markman*, 517 U.S. at 390.

* * *

MFV began this controversy by asserting that Medtronic's new cardiac resynchronization devices infringe its patents and demanding payment. MFV could hardly have been surprised that Medtronic filed a declaratory judgment action demanding adjudication of MFV's accusation; indeed, the parties' contract envisioned just that. The Federal Circuit erred in ruling that Medtronic's status as a nominal plaintiff and the absence of a counterclaim somehow triggered a presumption that MFV's monopoly covered Medtronic's independently developed products. Rather, an assertion of infringement and demand for royalties—whether made in a letter or in a civil complaint—remains a demand that the recipient pay for the right to market otherwise-lawful goods. It is entirely appropriate to require a patentee making such a demand to justify its contention.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

MARTIN R. LUECK
Counsel of Record
JAN M. CONLIN
STACIE E. OBERTS
ROBINS, KAPLAN, MILLER
& CIRESI LLP
2800 LaSalle Plaza
800 LaSalle Ave.
Minneapolis, MN 55402
(612) 349-8500
mrlueck@rkmc.com

SETH P. WAXMAN
PAUL R. Q. WOLFSON
BRIAN H. FLETCHER
CAROLYN JACOBS CHACHKIN
WEILI J. SHAW
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006

MARK C. FLEMING
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109

JULY 2013

RESPONDENT'S BRIEF

No. 12-1128

IN THE

Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

BOSTON SCIENTIFIC CORPORATION,
GUIDANT CORPORATION, AND MIROWSKI FAMILY
VENTURES, LLC,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT MIROWSKI FAMILY VENTURES

SIDNEY J. SILVER
SILVER, FREEDMAN &
TAFF, LLP
3299 K Street, N.W.
Washington, D.C. 20007
(202) 295-4500

ARTHUR I. NEUSTADT
Counsel of Record
THOMAS J. FISHER
JOHN F. PRESPER
OBLON, SPIVAK, MCCLELLAND,
MAIER & NEUSTADT, LLP
1940 Duke Street
Alexandria, VA 22314
(703) 413-3000
aneustadt@oblon.com

Counsel for Respondent Mirowski Family Ventures

QUESTION PRESENTED

Mirowski Family Ventures, LLC ("Mirowski" or "MFV"), being dissatisfied with Medtronic's Question Presented (S. Ct. R. 24.2), submits the following Question Presented.

As to burden of proof, "the normal rule [is to] allocat[e] the burden to the party seeking relief." *Schaffer v. Weast*, 546 U.S. 49, 55 (2005). Further, "while the normal default rule does not solve all cases, it certainly solves most of them. Decisions that place the *entire* burden of persuasion on the opposing party at the *outset* of a proceeding -- as petitioners urge us to do here -- are extremely rare." *Id.* at 57, emphasis by Court.

Accordingly, in a declaratory judgment ("DJ") action by a patent licensee against its licensor, where the licensor cannot counterclaim for infringement (since the licensee is licensed), and the licensor does not seek any relief, *is* the burden of proof on claim coverage governed by the normal default rule (the party seeking relief has the burden) or is this one of the "extremely rare" cases where the party not seeking any relief (the patentee) has the burden.

CORPORATE DISCLOSURE STATEMENT

Mirowski Family Ventures, LLC is a limited liability company, which is not publicly traded. It has no parent corporation and no publicly held company owns 10% or more of its stock.

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§ 337, p. 412 (5th ed. 1999)...................................*16*

C. Mueller & L. Kirkpatrick, *Evidence*
§ 3.1, p. 104 (3d ed. 2003).. 16

IN THE
Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

BOSTON SCIENTIFIC CORPORATION,
GUIDANT CORPORATION, AND MIROWSKI FAMILY
VENTURES, LLC,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT MIROWSKI FAMILY VENTURES

INTRODUCTION

Medtronic's brief on the merits, the *amicus* brief for the United States submitted by the Solicitor General and the Patent and Trademark Office ("SG/PTO") and the *amicus* brief submitted by the "Legal Scholars" all suffer from the same critical defect – each ignores the normal default rule (the party seeking relief bears the burden of proof) and incorrectly assumes that a patentee *always* bears the burden, even when the patentee is not asserting infringement or seeking any relief.[1]

The first step in applying the normal default rule is to ascertain whether one or both parties are seeking relief. If only one party is seeking relief, as in this case, the rule is easy to apply and the party seeking relief (Medtronic) has the burden. If both parties are seeking relief, the rule is not as easy to apply but that is not the case here.

The briefs submitted by Medtronic, the SG/PTO and the Legal Scholars are largely directed to applying the rule where both parties are seeking relief.[2] However, the case at bar does not involve this issue since Medtronic is the only party seeking relief.

The briefs submitted by Medtronic, the SG/PTO and the Legal Scholars do not argue that this case is one of those "extremely rare" cases where the burden is on the party not seeking any relief. Rather, these briefs largely ignore this normal default rule.[3]

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[1] The term "seeking relief" refers to seeking relief in the DJ action and does not refer to, as Medtronic asserts, that Mirowski will benefit if Medtronic does not win its DJ action.

[2] For example, such a case could involve an accused infringer filing a non-infringement DJ action and the patentee filing an infringement counterclaim.

[3] Medtronic's brief devotes only one half page (28) to *Schaffer*, summarily dismissing it as not involving a DJ action. Presumably Medtronic is not saving its argument for its reply brief.

STATUTORY PROVISION INVOLVED

35 U.S.C. §271 entitled "Infringement of patent" states

> (a) Except as otherwise provided in this title, whoever *without authority* makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

Emphasis added.

STATEMENT

A. The ICD and CRT Inventions

Michel Mirowski, M.D., a practicing cardiologist, is generally regarded as the father of the implantable cardioverter defibrillator ("ICD"). Most people are familiar with the hospital scene where a patient's heart suddenly stops beating but the patient is saved by an electrical shock administered through paddles after the doctor gives the command to "Clear!"

Some people are unfortunate enough to have their heart stop beating when they are not in the hospital. These people often die within five minutes of "sudden cardiac death" since the brain can no longer survive without the oxygen provided by the beating heart.

The ICD is small enough to be implanted in the chest. It senses when the heart stops beating (fibrillation) and, in response thereto, provides the shock that saves the patient's life by causing the heart to start beating again.

In 2002, Dr. Mirowski was posthumously inducted into the National Inventors Hall of Fame for his ICD invention. The "Invention Impact" from his Hall of Fame profile states:

> Facing formidable opposition from the medical community, Mirowski led a team that designed and tested the first ICD, which was also the first alternative to drugs and surgery. The first human implant occurred in 1980. ... The device has saved hundreds of thousands of patients worldwide.

Available at ww.invent.org/hall_of_fame/175.html. *See, also.* Mehta, NJ and Khan, IA, "Cardiology's 10 Greatest Discoveries of the 20th Century," *Tex Heart Inst J.* 2002; 29(3): 164–171, available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC124754

Morton Mower, M.D., also a practicing cardiologist, was a co-inventor with Dr. Mirowski on the invention of the ICD and was also inducted into the National Inventors Hall of Fame. The "Invention Impact" from his Hall of Fame profile states:

> Normally, a natural pacemaker within the heart stimulates it to contract,

> producing a heartbeat. Ventricular fibrillation occurs when impulses from the heart's ventricles signal the heart to beat abnormally, causing very little blood to be pumped through the heart to the brain and body, which can result in sudden cardiac death. One reason the AICD [automatic ICD] is successful is because it treats ventricular fibrillation within seconds, preventing sudden cardiac death.

Available at www.invent.org/hall_of_fame/176.html

In the 1980s, while still a practicing cardiologist, Dr. Mower recognized that the ICD, despite its overwhelming success in saving lives, did not address the many lives lost each year from congestive heart failure. Dr. Mower also recognized that a patient could be saved by an ICD only to subsequently succumb to more prevalent chronic congestive heart failure. District court decision, Pet. App. 28a.

In response to this need, Dr. Mower invented cardiac resynchronization therapy ("CRT"), which uses a modified implanted pacemaker to continuously coordinate the contractions of the left and right ventricles of the heart, which significantly improves the heart's pumping ability.[4]

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[4] Mirowski's Federal Circuit blue brief ("Blue Brief"), filed July 13, 2011, at 6-8, 10-11. The Blue Brief cites to the evidence in the Federal Circuit Joint Appendix ("FCJA").

Medtronic describes CRT as "a revolutionary new approach to managing heart failure," "a proven treatment for selected patients with ... ventricular dyssynchrony," and "designed to reduce symptoms and improve cardiac function." Mirowski Blue Brief at 8-10.

Dr. Mower's treatment is so effective and beneficial that it has become the standard of care today for the treatment of advanced heart failure. FCJA at 1499, 1525-26.

B. The Term "Infringement"

By definition, a non-breaching patent licensee cannot be an infringer. 35 U.S.C. §271(a) ("[W]hoever *without authority* makes uses, offers to sell, or sells any patented invention ... during the term of the patent therefor, infringes the patent." Emphasis added. Because Medtronic's license provided it *with authority*, Mirowski had no basis for counterclaiming that Medtronic was an infringer.[5]

The term "infringement" has another, albeit legally incorrect, meaning. When this term is used in a patent license (as it was in the 1991 license and the 2006 LTA), it means "claim coverage" because the licensee cannot be an infringer.[6] Medtronic in its brief on the merits, conflates these two meanings, which makes its legal arguments, especially with reference to case law, difficult to understand or analyze.

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[5] The pre-trial order submitted by Medtronic and Mirowski (Joint Appendix ("JA") at 1 (# 177), which was "so ordered" by the district court (JA12), states – "Since Medtronic is a licensee, it cannot be an infringer." JA51.

C. The 1991 License

In 1991, Eli Lilly & Co. ("Lilly") was Mirowski's exclusive licensee. In 1983, Lilly's predecessor in interest brought suit against Medtronic in the Philadelphia federal court (E.D. Pa.) for patent infringement with respect to Medtronic's sales of its ICD products. The district court, the Federal Circuit, and this Court rendered decisions in this 1983 case. The case was ultimately settled by Lilly and Medtronic with the 1991 license.[7]

Both Lilly and Medtronic were major players in the ICD market. The 1991 license was primarily a "fully paid up" (royalty free) cross-license in which Medtronic and Lilly broadly cross-licensed each other's patents in the heart stimulator field. JA10-

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[6] The pre-trial order states – "The term 'infringement' is used in the LTA [Litigation Tolling Agreement] to indicate claim coverage." JA51.

[7] *Eli Lilly & Co. v. Medtronic, Inc.*, 1988 U.S. Dist. LEXIS 17587 (E.D. Pa. 1988); 696 F.Supp. 1033 (E.D. Pa. 1988); 872 F.2d 402 (Fed. Cir. 1989); 879 F.2d 849 (Fed. Cir. 1989); 735 F.Supp. 652 (E.D. Pa. 1990); 496 U.S. 661 (1990); 915 F.2d 670 (Fed. Cir. 1990).

12, 17. The license identifies over 300 Medtronic patents and over 100 Lilly patents.[8]

The cross-license included not only patents owned by Medtronic and Lilly but, also, patents owned by third parties that Medtronic or Lilly had the right to sublicense. JA12-13. If the third party license required a royalty, Medtronic and Lilly agreed that the royalty would be paid by the sublicensee. JA12. Lilly, as Mirowski's exclusive licensee, had a right to sublicense Mirowski's patents. The royalty was 3% for each ICD device which Medtronic agreed to pay. JA53.

The 1991 license specifically provided for the license of Mirowski's patents. JA13. These patents included Mirowski's ICD patents and also the parent ('688) patent for Dr. Mower's CRT invention and any reissue thereof. JA9, 17. The '119 and '897 patents in the case at bar were reissue patents of the parent '688 patent.[9]

The 1991 license specifically provided for any "new Medtronic devices." JA13. If Medtronic was not paying royalties on any new device, and if Lilly or Mirowski believed that this device was covered under the license, Lilly would provide such notice to Medtronic.

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[8] FCJA at 8014-8025, 8029-8032.

[9] The '688, '119 and '897 abbreviations refer to the last three numbers of each patent. The full numbers are 4,928,688, RE38,119 and RE39,897.

If Medtronic paid the royalty, the license provided that it had the right to challenge claim coverage, validity, and enforceability through a DJ action that it would bring. In this DJ action, Lilly/Mirowski could not seek an injunction, damages, or willful infringement. If Medtronic won its DJ action, the royalties paid by Medtronic from the date suit was filed would be refunded. If Medtronic lost, it could not recover these royalties. JA13.

D. The 2006 Litigation Tolling Agreement

In 2003, the PTO issued the '119 CRT patent. In 2004, Guidant/Mirowski brought suit against St. Jude Medical, Inc. ("St. Jude") in the Delaware federal court (D. Del.) for infringement of this patent. JA20.

Medtronic, Guidant (a spun-off Lilly subsidiary that became Mirowski's exclusive licensee) and Mirowski all recognized that the decision in the Delaware case against St. Jude could impact any subsequent DJ action by Medtronic for its new CRT products. Because Medtronic routinely introduced new CRT products, this could involve a number of DJ actions.

Medtronic did not want the expense of bringing a DJ action for each new CRT product. Similarly, Guidant did not want the expense of defending so many actions. Accordingly, in 2006, they (and Mirowski) agreed to toll the need for Medtronic to file any DJ action until after a final decision in the St. Jude case, or October 1, 2007, whichever came later. JA20-21. This agreement referred to a "Final DJ

Action" in lieu of an action each time Medtronic introduced a new CRT product. JA21. This case is this Final DJ Action.

Medtronic had already filed one such DJ action. In 2003, Medtronic filed a DJ action in Delaware (D. Del.) for its first generation CRT products. By agreement, this suit was limited to the "recapture" and "reissue oath" validity issues. A bench trial was held in 2004, the district court ruled for Guidant/Mirowski in 2005 and the Federal Circuit affirmed in 2006.[10]

This 2003 DJ action decided the issue for the 3% royalties for Medtronic's first generation CRT products. The LTA covered the second and subsequent generations of Medtronic CRT products. JA21-22 ("Second Products" and "Subsequent Products").

The 2006 LTA does not differ in any significant respect from the 1991 license as to Medtronic's right to file a DJ action to challenge its obligation to pay royalties. JA23-24. The LTA did, however, permit Medtronic to deposit the withheld royalties in a separate account under its control, with these royalties to be distributed in accordance with the decision in the final DJ action. If Medtronic wins, it can keep the royalties. If it loses, the royalties are to be paid to Mirowski (with interest). JA27-28.

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[10] *Medtronic Inc.. v. Guidant Corp.*, 378 F. Supp. 2d 503 (D. Del. 2005), *aff'd*, 465 F.3d 1360 (Fed. Cir. 2006).

Medtronic in its brief states (at 13, n.6) that the withheld royalties (with interest) to date are $120M. Without the interest, this would indicate that Medtronic had $4B in sales of its CRT products. With the interest, the $120M would indicate sales in excess of $3B. Either way, it was a highly successful business for Medtronic. This suit is Medtronic's attempt to avoid paying the 3% royalty on its greater than $3B in sales of its second and subsequent CRT products.

To date, by agreement, Medtronic has not paid any royalty to Mirowski for these sales. This was similar to Medtronic's first generation CRT products (noted above) where, also by agreement, Mirowski obtained no royalty until after the Delaware district court ruled in its favor and the Federal Circuit ruled against Medtronic in its appeal.

Medtronic's license as applied to its CRT products provided it with many benefits. It did not have to pay royalties when it sold its CRT products. It merely had to withhold them and file a DJ action. If it won, it paid nothing. If it lost, it only had to pay the 3% royalty (with interest). Further, the license provided freedom to use Dr. Mower's CRT invention, which shielded Medtronic from an injunction, damages, and willful infringement.

Medtronic, in this action, seeks an even better deal.

E. The District Court Proceedings

Medtronic filed the final DJ action against Mirowski in 2007. Medtronic asserted non-infringement (claim coverage), invalidity, and unenforceability. Mirowski filed no counterclaim.[11]

After a five-day trial and post-trial briefing, the district court held against Medtronic on validity and enforceability, but against Mirowski on infringement (claim coverage), holding that Mirowski had the burden on this issue and had not sustained it.

As to infringement (claim coverage), Medtronic asserted that Mirowski's expert Dr. Berger had not covered in his expert report each of the elements of the patent claims at issue. However, Medtronic declined to identify even one element that Dr. Berger had supposedly not covered in his report.

After post-trial briefing, and presumably reluctant to rule against Mirowski on this issue without identifying at least one element that had not been covered in Dr. Berger's report, the district court *sua sponte* undertook its own review, and (erroneously) concluded that Dr. Berger's report did not cover the "sense amplifier" (which was recited in a few of the claims at issue but was not included in most of them). On this basis, the district court then held that Mirowski had not sustained its supposed burden as to

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[11] Medtronic demanded a jury trial. Mirowski moved to quash since Medtronic only requested equitable relief (a declaration). The district court granted the motion. *Medtronic, Inc. v. Boston Scientific Corp.*, 587 F.Supp. 2d 648, 656-57 (D. Del. 2008).

all claims at issue, whether or not they recited a sense amplifier.

The district court erred for a number of reasons. First, Dr. Berger's report did include the sense amplifier.[12] Second, most of the claims at issue in both the '119 and '897 patents did not recite a sense amplifier and, therefore, did not require its presence.[13] Third, Medtronic's engineer Ms. Kleckner, who had helped design Medtronic's CRT products, testified at trial that these products did include the sense amplifier.[14]

Fourth, Medtronic had limited the infringement issues through discovery so as not to include the sense amplifier.[15] Fifth, since Mirowski did not (and could not) counterclaim for infringement, Medtronic was the only party requesting any relief and, therefore, had the burden.

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[12] Mirowski Blue Brief at 39-41. Mirowski yellow brief ("Yellow Brief") before the Federal Circuit, filed November 18, 2011, at 21-23. The Yellow Brief, like the Blue Brief, cites to the evidence in the FCJA. The sense amplifier is discussed in detail at pages 43-44 of Dr. Berger's report. FCJA at 2243-44.

[13] Mirowski Blue Brief at 6, 41-42, Mirowski Yellow Brief at 24. A specific identification of the claims at issue of the '119 and '897 patents that do not recite a sense amplifier is in the Mirowski Blue Brief at 6, n.5.

[14] Mirowski Blue Brief at 49-53, Mirowski Yellow Brief at 27-29.

[15] Mirowski Blue Brief at 49-53, Mirowski Yellow Brief at 27-29.

Sixth, wearing belt and suspenders, Mirowski proved claim coverage at trial despite the fact that it had no burden to do so. Dr. Berger's testimony at trial (and his expert report) applied each element of each claim at issue, including the sense amplifier, to each Medtronic CRT device.[16]

The district court also erred by not recognizing that the "insubstantial differences" test was a recognized test for proof of doctrine of equivalents infringement (claim coverage).[17]

F. The Federal Circuit Proceedings

The Federal Circuit addressed only the claim coverage burden and held that Medtronic, not Mirowski, had this burden because Medtronic was the only party seeking relief.

> Medtronic is unquestionably the party now requesting relief from the court: it already has a license; *it cannot be sued for infringement; it is paying money into escrow; and it wants to stop.* In contrast, regarding the patents at issue here, *MFV seeks nothing more than to be discharged from the suit* and be permitted to continue the quiet enjoyment of its contract. [footnote omitted].

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[16] Mirowski Blue Brief at 16-27.

[17] Mirowski Blue Brief at 55-60, Mirowski Yellow Brief at 33-36.

Pet. App. 12a (emphasis added).

The Federal Circuit further held that it was Medtronic, not Mirowski, that sought to disturb the status quo.

> In other words, *it is Medtronic and not MFV that is asking the court to disturb the status quo ante* and to relieve it from a royalty obligation it believes it does not bear. Consistent with the above, *for the court to disturb the status quo ante, Medtronic must present evidence showing that it is entitled to such relief. If neither party introduced any evidence regarding infringement or noninfringement there is no principled reason why Medtronic should receive the declaration of noninfringement it seeks.*

Pet. App. 12a-13a (emphasis added).[18]

The Federal Circuit relied upon *Schaffer* in holding that the party seeking relief (Medtronic), bears the burden of proving the allegations in its DJ complaint.

> Generally, *the party seeking relief bears the burden of proving the allegations in his complaint. See Schaffer ex rel.*

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[18] The Federal Circuit could have referred to "claim coverage" rather than "infringement" since Medtronic as a non-breaching licensee could not infringe.

> *Schaffer v. Weast*, 546 U.S. 49, 56-57 (2005). "Perhaps the broadest and most accepted idea is that the person who seeks court action should justify the request ...." *Schaffer*, 546 U.S. at 56 (quoting C. Mueller & L. Kirkpatrick, *Evidence* § 3.1, p. 104 (3d ed. 2003)). "*The burdens of pleading and proof with regard to most facts have been and should be assigned to the plaintiff who generally seeks to change the present state of affairs and who therefore naturally should be expected to bear the risk of failure of proof or persuasion.*" *Id.* (quoting 2 J. Strong, *McCormick on Evidence* § 337, p. 412 (5th ed. 1999)).

Pet. App. 9a-10a (emphasis added).

The Federal Circuit further held that Mirowski did not have the burden because it did not (and could not) counterclaim for infringement.

> And in the customary declaratory judgment case, ... the declaratory judgment defendant must assert a counterclaim for infringement to avoid risking the loss of that claim forever. *See id. But this is not such a case. In this case, ... the continued existence of the license precludes the very infringement counterclaim that normally would impose the burden of proving infringement on the patentee.*

> *Here, Medtronic is shielded from any liability for infringement by its license. And MFV has not asserted a claim of infringement, nor could it because of the license.*

Pet. App. 12a (emphasis added).

The Federal Circuit also held that "the one claim for relief sought in this case" was by Medtronic and it, not Mirowski, should bear the burden on this claim.

> As noted, neither party here seeks money damages or an injunction based on patent infringement, which are the sorts of relief generally sought when a party seeks relief for patent infringement. *Instead, the one claim for relief sought in this case is the claim Medtronic asserts to be relieved from liability under the license by having a court declare the products in question to be noninfringing. Medtronic is the party seeking this relief and Medtronic must bear the burden of proving it is entitled to such relief.*

Pet. App. 14a (emphasis added).[19]

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[19] The Federal Circuit could have used the language "not covered by the claims" rather than "noninfringing" since Medtronic, as a non-breaching licensee, could not infringe.

To hold otherwise would allow licensees "to use *MedImmune's* shield as a sword."

> *A contrary result would allow licensees to use MedImmune's shield as a sword -- haling licensors into court and forcing them to assert and prove what had already been resolved by license.* Because the declaratory judgment plaintiff is the only party seeking the aid of the court in the circumstances presented here, that party must bear the burden of persuasion.

Pet. App. 14a (emphasis added).[20]

The Federal Circuit pointed out that the result in this case was highly dependent upon "the limited circumstance" of an infringement counterclaim being foreclosed by the continued existence of a license.

> Therefore, this court holds that in *the limited circumstance when an infringement counterclaim by a patentee is foreclosed by the continued existence of a license*, a licensee seeking

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[20] Contrary to Medtronic's assertion (at 40-43), the Federal Circuit was not saying that coverage with respect to the "new" product could not be challenged, but that Medtronic wanted and obtained a license for the new product and, after doing so, should not be able to bring suit against Mirowski and say that it has no responsibility to prove non-claim coverage as asserted in its complaint.

> a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion.

Pet. App. 14a (emphasis added).[21]

G. Medtronic's "*Under Sea*" Argument

Medtronic's primary argument before the district court, the Federal Circuit and this Court (in its petition for certiorari) was that Mirowski was trying to shift the burden. A "shift" presupposes an earlier position and a subsequent "shifted to" position. Medtronic's "earlier position" was the Federal Circuit's "always" statement in *Under Sea v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) that "[t]he burden *always* is on the patentee to prove infringement." Emphasis added.

Because Medtronic's asserted "earlier position" is baseless, there has been no "shift" in the burden. In fact, it is Medtronic, and not Mirowski, that is trying to shift the burden contrary to the normal default rule that the party seeking relief should bear the burden.

Not surprisingly, the Federal Circuit did not agree that Medtronic's quoted "always" sentence from *Under Sea* meant that the patentee always has the burden. This was because *Under Sea* was only a traditional (non DJ) infringement action in which the patentee asserted infringement. The *Under Sea* district court erroneously placed the burden of proving non-infringement on the accused infringer and the Federal Circuit simply held that this was error.

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[21] The Federal Circuit could have stated "a declaratory judgment of no claim coverage" rather than "a declaratory judgment of noninfringement."

> The district court erred to the extent it apparently placed the burden on Dacor [accused infringer] of showing noninfringement. The burden always is on the patentee to show infringement.

833 F.2d at 1557.[22]

Contrary to Medtronic's assertion, *Under Sea* only holds that a patentee who asserts infringement has the burden which is entirely consistent with the normal default rule.

The applicable law as to who has the burden is not *Under Sea* but *Schaffer* which holds "that the burden lies, as it typically does, on the party seeking relief," "the normal rule [is to] allocat[e] the burden to the party seeking relief," "the ordinary default rule [is] that plaintiffs bear the risk of failing to prove their claims," the burden "should be assigned to the plaintiff who generally seeks to change the present state of affairs," "the broadest and most accepted idea is that the person who seeks court action should justify the request," "we have usually assumed without comment that the plaintiffs bear the burden of persuasion regarding ... their claims" and "the burden of persuasion lies where it usually falls, upon the party seeking relief." 546 U.S. at 57-59

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[22] The Federal Circuit in this statement used the term "infringement" in its legally correct sense. *Under Sea* involved infringement and not claim coverage.

H. Medtronic's Abandonment of Its *Under Sea* Argument in Favor of Its New *Lear* Argument

Medtronic's *Under Sea* "always" argument was successful before the district court which held that "'[t]he burden is always on the patentee to show infringement.' *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) ... ." Pet. App. 40a. Medtronic repeated this argument to the Federal Circuit, but without success. Medtronic then made this same argument to this Court in its petition for certiorari (at 7-8).

Surprisingly, after winning before the district court with its *Under Sea* argument, and having its petition for certiorari granted by this Court, Medtronic abandoned this argument in its brief on the merits. In its stead, Medtronic presents a new argument based upon *Lear v. Adkins*, 395 U.S. 653 (1969). This argument was not previously presented or considered.[23]

In *Lear*, this Court overruled the doctrine of licensee estoppel. This doctrine held that a licensee could not challenge invalidity because the licensee would not have agreed to the license had he not thought that the licensed patent was valid. If the licensee did not pay royalties, the licensor could bring suit for enforcement of the license or for patent infringement, at its option. This Court stated that it was necessary to "unmuzzle" the licensee so that it could assert invalidity as a defense to any suit by the licensor. 395 U.S. at 673.

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[23] Medtronic, in its briefing before the Federal Circuit and in its petition for certiorari before this Court, cites to *Under Sea*, but not to *Lear*, and, in its recently filed brief on the merits, cites to *Lear*, but not to *Under Sea*.

Medtronic's *Lear* argument appears to be that this Court should now "unmuzzle" the licensee (Medtronic) as to claim coverage by holding that the patentee (Mirowski), although not seeking any relief in the licensee's DJ action, should have the burden to disprove the licensee's claim that its products are not covered by the license.

This argument makes no sense whatsoever. In *Lear*, this Court left untouched who had the burden as to invalidity (the licensee). Since the 1991 license and the 2006 LTA both gave Medtronic the right to challenge claim coverage with a DJ action, Medtronic has always been "unmuzzled."

Since Medtronic's *Lear* argument was not presented to or considered by the Federal Circuit (or in Medtronic's petition for certiorari), this Court should refuse to consider it.

SUMMARY OF ARGUMENT

Medtronic is the only party seeking relief. Mirowski could not counterclaim since Medtronic was licensed to practice Dr. Mower's CRT invention. Thus, under the normal default rule, Medtronic bears the burden of proving entitlement to the relief that it seeks.

Medtronic's new *Lear* argument should not be considered since it was not presented to or considered by the Federal Circuit. Nor was it included in Medtronic's petition for certiorari. Further, this argument is baseless. *Lear* is not a burden of proof case. Also, Medtronic has always been "unmuzzled."

Mirowski as the party not seeking any relief should not have the burden to prove claim coverage simply because patentees asserting infringement in traditional infringement actions must prove infringement. Patentees asserting infringement have to prove infringement, not because they are patentees, but because they are asserting infringement (and seeking relief based on this infringement).

Medtronic also has the burden on claim coverage since the 1991 license and the 2006 LTA required Medtronic to bring the DJ action if it wanted relief from its license. The license and the LTA could have specified that Mirowski had to bring the DJ action, but they did not. Rather, they specified that Medtronic would bring this action.

If the licensor bears the burden on claim coverage, it will create a strong disincentive for a patentee to settle an infringement dispute with a license. Why license the patent to settle an infringement dispute when the next day the licensee can file a *MedImmune*-type DJ action and insist that the patentee prove claim coverage (as it would have to do in an infringement action) when the patentee by licensing the patent (the day before) lost the right to seek an injunction, damages and willful infringement?

Medtronic's arguments "proving a negative," "hundreds of claims" and "under any possible theory," which were not presented to or considered by the Federal Circuit, are baseless. As to "proving a negative," under the all elements or all limitations rule, it is easier, not harder, to prove noninfringement (than to prove infringement). As to "hundreds of claims," it does not matter how many claims are in a patent, it is only the claims in dispute, and these claims have to be limited in order to make the case manageable. As to "under any possible theory," patent litigants need not anticipate each other's arguments. Only after an argument is made is a response necessary.

Subject matter jurisdiction is present. If not, this case should be remanded to the Federal Circuit with instructions to transfer this appeal to the Third Circuit (the district court was in Delaware) pursuant to 28 U.S.C. §1631 to decide the appeal after determining the presence of diversity jurisdiction. There was diversity jurisdiction before the district court, which would have made an appeal to the Third Circuit appropriate if it is determined that the Federal Circuit did not have subject matter jurisdiction.

If it is determined that Mirowski has the burden, this case should be remanded to the Federal Circuit to consider the district court's errors that were mooted by the Federal Circuit's burden of proof decision. These errors were a primary focus of Mirowski's appeal to the Federal Circuit. It would be a denial of Mirowski's right to appeal an adverse judgment if these errors were unmooted by a decision by this Court and then not considered by the Federal Circuit after this Court's decision.

ARGUMENT

I. Since Medtronic Is The Only Party Seeking Relief, It Bears The Burden Under The Normal Default Rule.

As previously noted, the normal default rule is easy to apply in this case since only one party (Medtronic) is seeking relief. Further, Medtronic does not argue that this is one of those "extremely rare" cases in which the party not seeking any relief bears the burden. Rather, Medtronic, for some reason, directs its arguments to those situations (not present in the case at bar) where both parties are seeking relief.

For example, Medtronic argues (at 18-23) that "the nominal reversal of traditional party status in a declaratory judgment action does not alter the substantive law's allocation of the burden of proof." However, this issue concerns cases in which both parties (such as the accused infringer and the counterclaiming patentee) are seeking relief. The case at bar is not such a case.

Medtronic also argues (at 23-28) that "the allocation of the burden of proof is a rule of substantive law that is not altered by the Declaratory Judgment Act." However, this issue likewise concerns cases in which both parties are seeking relief and the case at bar is not such a case.

Medtronic further argues (at 34-38) that "substantive patent law assigns the burden of proving infringement to the patentee, and that burden does not shift when a patent licensee seeks a declaratory judgment of non-infringement," "federal patent law places the burden of proving infringement on the patent holder" and "a suit seeking a declaration of noninfringement is simply an inverted infringement action and does not shift the burden to the accused infringer."

Although Medtronic's argument is debatable if it is referring to infringement, not claim coverage, it is claim coverage and not infringement that is at issue here. Where the issue is claim coverage between a non-breaching licensee and its licensor as is the case here, Medtronic's argument fails completely and Medtronic has cited no case whatsoever from this Court or any other appellate court with such a holding.

Medtronic also argues (at 38-39) that "the presence or absence of an infringement counterclaim is immaterial." Medtronic's argument is baseless. If there is an infringement counterclaim (both parties are seeking relief), it is an inverted infringement suit and the patentee has the burden. However, if a counterclaim is precluded (by a license), the normal default rule applies and the party seeking relief (the licensee) bears the burden.

Medtronic also argues (at 39) that a licensor can "bring a claim or counterclaim for a *declaratory judgment* of infringement or claim coverage, even where no actual infringement has yet occurred." Emphasis by Medtronic. However, the quoted language from the case that Medtronic cites in support of this proposition refers only to "infringement" and, therefore, is not applicable to a licensor-licensee situation. Further, there would be no "controversy" in the licensor-licensee situation where the licensee is paying the royalties. If not, the licensee would be subject to a suit for infringement. Also, Mirowski filed no such counterclaim in the case at bar.

Medtronic further argues (at 39-43) that "the Federal Circuit's concerns about *MedImmune*-type litigation do not justify its deviation from the standard allocation of the burden of proof." However, there was no "deviation." The standard allocation of the burden of proof is the normal default rule and it was followed in this case. Medtronic simply ignores this all important rule as supposedly not applying to DJ actions.

Nor was the Federal Circuit "concerned" about *MedImmune* type cases. Rather, the Federal Circuit only held that in these cases where the licensee files a DJ action for non-claim coverage and the patentee cannot counterclaim for infringement, the normal default rule is applicable and the licensee has the burden on claim coverage.

Medtronic asserts (at 41) that Mirowski "needs a judicial determination of infringement in order to have a right to a payment of such royalties." Medtronic then cites to the phrase in the LTA concerning Medtronic products that "were held to infringe." However, this refers to those Medtronic products in a split decision as to which Medtronic did not prevail in its DJ action. If Medtronic is now asserting a different meaning, it is an entirely new argument that was not presented to the Federal Circuit (or to this Court in Medtronic's petition for certiorari) and, therefore, should be excluded.

II. This Court Should Not Consider Medtronic's New *Lear* Argument That Was Not Included In Its Petition Nor Presented to the Federal Circuit.

As discussed *supra*, Medtronic in its brief on the merits has abandoned its *Under Sea* "always" argument which was the basis for its win before the district court and, in its stead, has asserted its new *Lear* argument (at 45-47). Medtronic unsuccessfully asserted its *Under Sea* "always" argument and did not present its *Lear* argument before the Federal Circuit. Thus, the Federal Circuit did not consider this argument.

Medtronic also did not present its new *Lear* argument in its petition for certiorari. Rather, this argument was not made until Medtronic's brief on the merits.[24]

Medtronic's new *Lear* argument attacks, rather than defends, the Federal Circuit's judgment. This Court has held that declining to consider such a new argument is "the better course."

> *We need not address the question, however.* Although in some instances we have allowed a *respondent* to defend a judgment on grounds other than those pressed or passed upon below, ... *it is quite a different matter to allow a petitioner to assert new substantive arguments attacking, rather than defending, the judgment when those arguments were not pressed in the court whose opinion we are reviewing, or at least passed upon by it.* Just this Term we declined an invitation by an *amicus* to entertain new arguments to overturn a judgment, ... and *we consider it the better course to decline a party's suggestion for doing so in this case.*

U.S. v. United Foods, Inc., 533 U.S. 405, 417 (2001) (emphasis added).

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[24] Medtronic's petition for certiorari lists four counsel for Medtronic. Medtronic's brief on the merits lists these four counsel and five new counsel.

The test is not whether Medtronic's new *Lear* argument is within its Question Presented. Rather, the test is whether the Federal Circuit considered this argument, which it did not.

> The Government argues the advertising here is government speech, and so immune from the scrutiny we would otherwise apply. *As the Government admits in a forthright manner, however, this argument was "not raised or addressed" in the Court of Appeals.* ... The Government ... suggests that the question is embraced within the question set forth in the petition for certiorari. In *Lebron*, the theory presented by the petitioner in the brief on the merits was addressed by the court whose judgment was being reviewed. ... *Here, by contrast, it is undisputed that the Court of Appeals did not mention the government speech theory now put forward for our consideration.*

Id. at 416 (emphasis added).

Likewise, this Court should not consider the almost identical argument in the SG/PTO brief filed one week after Medtronic's brief on the merits. *Cf.* Medtronic's brief on the merits (at 45) with the SG/PTO brief (at 31), each citing *Lear* ("full and free competition in the use of ideas") followed by a citation to *Blonder-Tongue Labs, Inc. v. University of Ill.*

Found., 402 U.S. 313, 349-50 (1971) ("exact royalties for the use of an idea").[25]

III. A Licensor Not Seeking Any Relief in a Licensee's DJ Action Should Not Have to Prove Claim Coverage Because, As Medtronic Asserts, It Has a Patent "Monopoly."

Medtronic's new *Lear* argument is that a defendant (patentee) not seeking any relief in a licensee's DJ action should have to prove claim coverage because it has a patent "monopoly."

This argument makes little sense. Although *Lear* "unmuzzled" the licensee to permit it to challenge validity, Medtronic has always been "unmuzzled" as to claim coverage by the 1991 license even prior to this Court's 2007 *MedImmune* decision.

At its core, Medtronic's argument is that a patentee should always have the burden, even if it is only a defendant not seeking any relief, since it has a "monopoly." The first Chief Judge of the Federal Circuit, Judge Howard T. Markey, explained this argument and its baselessness when he was sitting by designation in the Court of Appeals for the Sixth Circuit.

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[25] *Blonder-Tongue* was a collateral estoppel case, holding that a patentee was collaterally estopped from suing a second defendant in a second action after entry of a final judgment of invalidity in a first action (against a first defendant), where the patentee in the first action had a full and fair opportunity to defend against the charge of invalidity. The case at bar has no such collateral estoppel issue.

> Stahlin says its election to make and sell its "Tear Drop" duct after the initial injunction was to insure that Panduit "was not going to have a monopoly." It is not uncommon for an infringer-contemnor to wrap itself in the mantle of public defender against "monopoly," in reliance on an unthinking *monopolophobia* it mistakenly hopes to find in the courts.
>
> *The loose application of the pejorative term "monopoly," to the property right of exclusion represented by a patent, can be misleading.* Unchecked it can also destroy the constitutional and statutory scheme reflected in the patent system.

Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1160 n.8 (6th Cir. 1978) (emphasis added).[26]

As further held in *Panduit*, since a valid patent takes nothing from the public, it is not the same as a "monopoly" against which the anti-trust laws are directed.

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[26] Prior to the formation of the Federal Circuit in 1982, Judge Markey was Chief Judge of the Court of Customs and Patent Appeals ("CCPA"), a predecessor to the Federal Circuit. Judge Markey's decision in *Panduit* was while he was Chief Judge of the CCPA.

> If the patent be valid, it takes nothing from the public, as does the "monopoly" against which our anti-trust laws are directed. *On the contrary, it gives to the public, by definition, that which the public never before had.* That a patent, like stocks, bonds and other property, may be misused in a plan violative of an anti-trust law does not render the property right in the patent a monopoly in the anti-social, anti-competitive sense, any more than it does the property right in stocks and bonds.

Id., (emphasis added).

Panduit also quotes this Court's decision in *United States v. Dubilier Condenser Corp.* 289 U.S. 178, 186 (1933).

> *Though often so characterized, a patent is not, accurately speaking, a monopoly, for it is not created by the executive authority at the expense and to the prejudice of all the community except the grantee of the patent.*
>
> * * *
>
> The term "monopoly" connotes the giving of an exclusive privilege for buying, selling, working or using a thing which the public freely enjoyed prior to the grant. Thus a monopoly takes something from the people. *An inventor deprives the public of nothing which it*

> *enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge.*

Panduit, 575 F.2d at 1160 (emphasis added).

Further, the patent laws have a Constitutional basis. Article 1, Section 8 specifically provides that Congress has the power "to promote the science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

Thus, a defendant (patentee) not seeking any relief in a licensee's DJ action should not have to prove claim coverage merely because it supposedly has a "monopoly."

IV. A Licensor Not Seeking Any Relief in a Licensee's DJ Action Should Not Have to Prove Claim Coverage Because, As Medtronic Asserts, Patentees Asserting Infringement Have to Prove Infringement.

Medtronic prevailed before the district court on its *Under Sea* "always" argument. Mirowski's response has always been that *Under Sea* was a traditional infringement action where the patentee asserted infringement, the *Under Sea* district court erroneously saddled the accused infringer with proving non-infringement, and the Federal Circuit reversed (because a patentee asserting infringement has the burden to prove it).

Medtronic has never directly responded to this argument and its brief on the merits cites many other cases, including cases from this Court, involving similar traditional patent infringement actions where the patentee asserted infringement.[27] Thus, it appears to be Medtronic's position that Mirowski has the burden on claim coverage because patentees in traditional infringement actions, where they assert infringement, have the burden to prove it.

This argument makes no sense whatsoever. Patentees have the burden of proof on infringement in traditional infringement actions, not because they are patentees, but because they are asserting infringement and seeking relief (injunction, damages, and willful infringement) for such infringement.

Whether the patentee is seeking relief for infringement is critical. If it is seeking relief, it should have the burden of proving such infringement. If it is not seeking relief, there is no reason to saddle it with proving infringement. This is what the Federal Circuit held in this case and this is what this Court held in *Schaffer*.

It makes no sense at all to say, as Medtronic appears to be saying, that a defendant patentee (not seeking any relief) must prove claim coverage in its licensee's DJ action (even though it cannot assert infringement), simply because, in more common traditional infringement actions, the patentee has the burden of proving infringement.

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[27] For example, this Court's decisions in the 1800s in *Railroad Co. v. Mellon*, 104 U.S. 112, 119 (1881), *Cammeyer v. Newton*, 94 U.S. 225, 231 (1877) and Agawan Co v. Jordan, 74 U.S. (7 Wall.) 583, 609 (1869).

V. Medtronic Also Has the Burden On Claim Coverage Since the 1991 License and the 2006 LTA Require Medtronic to Bring the DJ Action (If It Wants Relief From Its License).

The 1991 license provided that Medtronic could file a DJ action *if* it wanted to seek relief from its license. The parties to this license were Lilly and Medtronic. It was an arm's length transaction. Lilly and Medtronic could have agreed that any dispute between them would be resolved by having Lilly file a DJ action. However, Lilly and Medtronic decided otherwise.

Rather, Lilly and Medtronic agreed that Medtronic would bring the DJ action if it wanted relief from its license. Thus, since the normal default rule is that the plaintiff bears the burden, Lilly and Medtronic agreed that Medtronic would bear the burden on claim coverage (if it wanted relief from its license).

There is no reason why Lilly and Medtronic could not make such an agreement, nor is there any reason why this agreement should not be enforced. Medtronic has never taken the position that the parties were not free to decide who would have the burden on claim coverage.

Medtronic's only response is that the agreement does not specify in *haec verba* who has the burden. However, the agreement effectively provides who has the burden by specifying that the DJ action is to be brought by Medtronic (if it wants relief from its license).

VI. Cases Involving a DJ Action For Non-Infringement (Not Claim Coverage) Are Inapposite Because a Counterclaim For Infringement Is Compulsory In Such an Action.

There is a significant difference between a DJ action for non-infringement and a DJ action for non-claim coverage. In the former, the patentee must counterclaim for infringement since it arises from the same "transaction or occurrence" as the DJ claim. Fed. R. Civ. P. 13(a)(1)(A). In contrast, in the latter, the patentee cannot counterclaim for infringement since the plaintiff/licensee is not an infringer (because of its license).

Medtronic (at 36) cites the statement in *Deere & Co. v. Sperry Rand Corp.*, 322 F.Supp. 397, 398 (E.D. Cal. 1970), *aff'd*, 513 F.2d 1131 (9th Cir. 1975) that "[t]he burden of proof in a declaratory judgment action involving patent infringement is on the defendant owner of the patents at issue ... just as if he were the plaintiff suing for infringement of those patents." However, *Deere* was a DJ action for non-infringement (not non-claim coverage) where the patentee counterclaimed for an injunction against infringement. *Id.* at 398.

Medtronic's citation to *Deere* includes footnote 15 which cites a number of similar cases.[28] However, each of these cases has the same critical defect as *Deere* – each case involves infringement (not claim coverage).

Immediately following Medtronic's citation to *Deere* is its assertion (at 36) that "[d]istrict courts have reached the same conclusion even where the declaratory judgment defendant did not counterclaim for infringement." Medtronic's footnote 16 cites a number of cases to presumably support this assertion. However, all of the cases in this footnote (with the exception of one) involve a DJ action for non-infringement where the patentee must assert infringement because it is compulsory.

The one exception noted above is *MedImmune, Inc.* v. *Centocor, Inc.*, 271 F. Supp. 2d 762, (D. Md. 2003). *Centocor* was a DJ action by a licensee for non-claim coverage where the district court made the same mistake made by the district court in the case at bar, *i.e.*, considering the "always" statement from *Under Sea* to mean that the patentee always has the burden, even if it cannot assert infringement. Accordingly, *Centocor* provides no support for Medtronic's assertion.

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[28] These cases are *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044 (Fed. Cir. 1988); *United Sweetener USA, Inc. v. Nutrasweet Co.*, 760 F. Supp. 400 (D. Del. 1991); *Advanced Transformer Co. v. Levinson*, 1986 WL 84365 (N.D. Ill. June 17, 1986); *Philip A. Hunt Co. v. Mallinckrodt Chem. Works*, 72 F. Supp. 865 (E.D.N.Y. 1947); *Vivid Techs., Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795 (Fed. Cir. 1999).

The *Centocor* district court also stated that it might decide the burden issue otherwise if presented with evidence of the "contractual intentions of the parties (*id.* at 770 n.11), a fact present in the case at bar since the parties agreed that Medtronic would file the DJ action (if it wanted relief from its license).

VII. If the Licensor Is Required to Have the Burden, as Medtronic Asserts, It Will Create a Strong Disincentive for a Patentee to Settle An Infringement Dispute with a License.

In *MedImmune*, the licensee filed a DJ action with respect to its new product. If *MedImmune* is not restricted to a new product, and if the patentee is assigned the burden on claim coverage, even though the patentee does not seek any relief, the following situation would likely act as a strong disincentive for a patentee to settle an infringement dispute with a license.

The patentee asserts infringement. The accused infringer wants to settle with a license. The patentee and the accused infringer agree upon a typical license. In this typical license, the patentee agrees not to sue the infringer for an injunction, damages, and willful infringement as long as the licensee pays the royalty.

The day after the license is signed, the licensee brings a *MedImmune* type action and tells the patentee that he (the licensee) does not have to prove non-claim coverage as asserted in his complaint but, rather, the patentee has to prove claim coverage as he would have to do in a traditional patent infringement action.

The patentee now realizes he has been severely disadvantaged. Proving claim coverage is what the patentee would have had to do in an infringement action. However, in an infringement action, the patentee could also seek an injunction, damages, and willful infringement. The patentee had the ability to do so before granting a license the day before. Now, he cannot do so. Thus, any patentee will now likely be quite reluctant to settle on such a basis since the patentee gives up a lot and receives very little.

The situation is not that different even if *MedImmune* is restricted to a new product. There may be a short time between the signing of the license and the introduction of the new product. Alternatively, even if the time is longer, the patentee will still suffer the loss of being able to seek an injunction, damages and willful infringement.

In such a situation, as stated by the Federal Circuit the licensee would be using "*MedImmune*'s shield as a sword." Pet. App. 14a.

VIII. Medtronic's Other Arguments Are Baseless

A. Medtronic's "*MedImmune*" Argument

In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), MedImmune (licensee) did not want to give up the protection of its license. If it did, its licensor (Genentech) could bring suit against it for an injunction, damages, and willful infringement. Accordingly, MedImmune continued to pay royalties.

MedImmune brought a DJ action. Genentech moved to dismiss the action because there was no "controversy" since MedImmune continued to pay its royalties. The Federal Circuit agreed, but this Court disagreed, holding that MedImmune did not have to "bet the farm" (breach its license) in order to challenge liability under the license.

This Court in *MedImmune* did not hold that Genentech would have the burden on claim coverage in MedImmune's DJ action. Genentech could not counterclaim for infringement because MedImmune was a licensee and not an infringer.

Medtronic's argument (at 45-47) appears to be that this Court would not have ruled for MedImmune on the "controversy" issue had it not wanted Genentech to have the burden on claim coverage. This makes no sense whatsoever. This Court ruled on the issue of "controversy" and did not consider, much less decide, the burden on claim coverage.

Medtronic's further argument that a *MedImmune* type licensee would not file a DJ action if it had the burden on claim coverage is both unsupported and, indeed, undermined by the *MedImmune* decision itself. *MedImmune* was worried about having to "bet the farm," not whether it might have the burden on claim coverage.

The Federal Circuit did not consider Medtronic's argument. Neither Medtronic nor Mirowski argued this Court's *MedImmune* decision before the Federal Circuit. Rather, both Medtronic and Mirowski agreed that Medtronic had a right to bring a DJ action pursuant to the 1991 license and the 2006 LTA. Neither party relied upon *MedImmune* for this right.

B. Medtronic's "Proving a Negative" Argument

Medtronic's "proving a negative" argument (at 43-45) was not presented to or considered by the Federal Circuit. If it had been presented, it would have been rejected as having nothing to do with proving non-infringement in a patent case. Medtronic cites no authority (other than non-patent cases) for its argument.

To prove infringement of a patent claim, it is necessary to show that the accused device has each element recited in the claim, either literally or by equivalents. This rule is known as the "all elements" or "all limitations" rule. To prove non-infringement, however, it is only necessary to show the absence of any one element. *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1484 (Fed. Cir. 1984)("non-infringement is shown when an element or step in the claims is missing from the accused product or process").

By way of example, a claim element may be "a nail" which connects together two other claim elements. The accused infringer might defend on the basis that the accused device uses a screw rather than a nail. If the accused infringer were successful with this defense, it would have, contrary to Medtronic's assertion, proved a negative without much difficulty. Thus, proving non-infringement is easier, not more difficult, than proving infringement.[29]

An accused infringer moving for summary judgment of non-infringement will have the burden to show "that there is no genuine issue as to any material fact and the [accused infringer] is entitled to judgment as a matter of law." Fed. R. Civ. P 56(a). Thus, if Medtronic were correct that non-infringement is unusually difficult to prove, there would be few, if any, motions for summary judgment of non-infringement, which the above example as well as common knowledge shows not to be true.

Less than three weeks ago, the Federal Circuit affirmed a summary judgment of non-infringement. *Applied Medical Resources Corp. v. Tyco Healthcare*

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[29] None of the cases cited by Medtronic have anything to do with the supposed difficulty of proving non-claim coverage (in comparison to proving claim coverage). Vieth v. Jubelirer, 541 U.S. 267, 311 (2004)(congressional redistricting); *NLRB v. Kentucky River Cmty. Care, Inc.*, 532 U.S. 706, 711 (2001)(unfair labor practice); *Elkins v. United States*, 364 U.S. 206, 218 (1960)(obscenity); *Piedmont & Arlington Life Ins. Co. v. Ewing*, 92 U.S. 377, 378-79 (1876)(insurance); *Arthur v. Unkart*, 96 U.S. 118, 122 (1878)(excessive duty); *Maxwell Land-Grant Co. v. Dawson*, 151 U.S. 586, 604 (1894)(ejectment to recover land); *Taylor v. Commissioner*, 70 F.2d 619, 621 (2d Cir. 1934)(tax deficiency); *United States v. Ollie*, 442 F.3d 1135, 1143 (8th Cir. 2006)(criminal case); *Cole v. Stevenson*, 620 F.2d 1055, 1065 (4th Cir. 1980)(murder case).

Group, No. 2012-1412 (Fed. Cir. August 27, 2013). The decision was Per Curiam and the disposition was "nonprecedential." Thus, "proving a negative" in this case was, contrary to Medtronic's assertion, not difficult or even remarkable.

C. Medtronic's "Hundreds of Claims" Argument

Medtronic's "hundreds of claims" argument (at 44-45) was not presented to or considered by the Federal Circuit. Had it been presented, it would have been rejected since it is the claims at issue, not the number of claims in a patent, that is determinative and patentees cannot put "hundreds of claims" at issue. District courts will not permit it because it would make a case unmanageable.

In this case, the LTA restricts the claims at issue (for all patents) to 30 claims. JA23, 26-27. Further, although Medtronic asserts that Mirowski during the case switched some claims, the LTA provided specific leave for Mirowski to do so as long as no more than 30 claims were asserted at any one time. JA26.[30]

If Medtronic's "hundreds of claims" argument is meant to refer to cases in the future and not to this case, there would also be no difficulty. Courts routinely restrict patentees to the number of claims they can put at issue. *In re Katz Interactive Call Processing Patent Litigation*, 639 F.3d 1303, 1309 (Fed. Cir. 2011) ("Katz [patentee] did not question the need to limit the number of claims in order to make the case manageable.")

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[30] The November 20, 2007 letter to Medtronic from Mirowski's counsel identifying the claims at issue identified only four claims from the '119 patent and 25 claims from the '897 patent. JA32. Further, Medtronic had only to prove non-claim coverage of the independent claims since a dependent claim cannot be infringed if its parent claim is not infringed. This left only three claims from the '119 patent and 20 claims from the '897 patent.

D. Medtronic's "Under Any Possible Theory" Argument

Medtronic's unsupported "under any possible theory" argument (at 44-45) was not presented to or considered by the Federal Circuit. Had it been presented it would have been rejected as baseless and, even, frivolous. An accused infringer filing a DJ action for non-infringement is not required to anticipate every argument that a patentee might make with respect to a counterclaim for infringement. Medtronic cites no case to support such a baseless proposition.

For example, if the claim recites a nail, and the accused device has a screw rather than a nail, the accused infringer might defend on the basis that one claim element (the nail) is missing. If the patentee responds that this screw is really a nail, the accused infringer can respond after considering the basis for the patentee's "really a nail" argument. There is no requirement that the accused infringer have a crystal ball to anticipate the patentee's "really a nail" argument.

E. Medtronic's "Affirmative Of the Issue" Argument

Medtronic's "affirmative of the issue" argument (at 43-44) is that, where one party asserts the affirmative of an issue and the opposing party asserts the negative, the party asserting the affirmative should have the burden. For example, if the accused infringer in a DJ action asserts non-infringement and the patentee responds with a counterclaim for infringement, then the patentee should bear the burden because it is asserting the affirmative of the issue. There is no dispute that the patentee would have the burden in this instance (even though the accused infringer filed a DJ action asserting non-infringement).

A different result obtains, however, where the patentee cannot counterclaim for infringement such as in the case at bar. In such a situation, the normal default rule is applicable and the party having the burden is the party seeking relief. Because the only party seeking relief in this case was Medtronic, it had the burden to prove its entitlement to the relief that it sought.

F. Medtronic's "Coercive" Argument

Medtronic's "coercive" argument throughout its brief appears to be that the party that has the burden is not the party who filed the DJ action but the party who asserted a "coercive" counterclaim in response thereto. This argument was not presented to or considered by the Federal Circuit. If it had been presented, it would have been rejected as not having any application to this case because Mirowski could not file a "coercive" infringement counterclaim since Medtronic was not an infringer.

G. Medtronic's "Mirowski Sought Relief" Argument

Medtronic implies throughout its brief that Mirowski was seeking monetary relief in Medtronic's DJ action because, if Medtronic lost, Mirowski would be entitled to the royalties that Medtronic had withheld. This argument is baseless.

Schaffer holds that the party seeking relief has the burden to show its entitlement to such relief. The seeking of relief is restricted to the seeking of relief *in the suit*. That Mirowski might benefit from Medtronic not prevailing in its DJ action does not mean that Mirowski was seeking relief *in the suit*. To seek relief in a suit means to file a claim or counterclaim. Mirowski did neither.

H. Medtronic's "Mirowski Asserted Infringement" Argument

The 2006 LTA provides that for any new Medtronic CRT product, Medtronic has to notify Guidant and Mirowski of this product and provide a manual therefor, Guidant or Mirowski then has to advise Medtronic as to any patent claims that cover this product and Medtronic can then either pay the royalty on this product or it can file a DJ action (if it wants to seek relief from its license). JA23-24.

In advising Medtronic as to claim coverage, Mirowski's counsel used the term "infringement" because both the 1991 license and the 2006 LTA required notice of "infringement," even though this is legally incorrect because Medtronic was licensed. JA13, 23-24. Thus, Medtronic's assertion (at 42-43) that Mirowski accused it of infringement (not claim coverage) is baseless.[31]

I. Medtronic's "Mirowski Started the Dispute" Argument

Medtronic appears to argue (at 47) that, if Mirowski had not given notice of "infringement" (claim coverage), there never would have been a suit and therefore, Mirowski should be considered as having filed the suit (even though Medtronic filed the suit and was the only party who sought relief).

Medtronic's argument is baseless. Medtronic filed the suit. It sought relief. It was not required to file any suit. It could have paid the royalties. Alternatively, it could have chosen not to pay the royalties (although it would have subjected itself to a suit for infringement). Mirowski did not dictate this situation. Rather, it was agreed to by Medtronic and it has no one to blame but itself if it no longer finds this situation to be to its liking.

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[31] The pretrial order specifies that "[t]he term infringement is used in the LTA to indicate claim coverage. Since Medtronic is a license, it cannot be an infringer." JA50-51. *See*, also JA1-2 (¶ 177).

J. Medtronic's "Nominal Plaintiff" Argument

Medtronic asserts (at 47) that it should not have the burden because it is only a "nominal" plaintiff. This argument is baseless. The normal default rule is that the party seeking relief bears the burden. There is no "nominal" plaintiff exception to this rule. A plaintiff cannot disassociate itself from its burden to prove its entitlement to the relief that it seeks by asserting that it is only a "nominal" plaintiff.

Pertinent in this regard is this Court's holding in *Schaffer* that, where both parties *could* seek relief, the burden is on the party that does seek relief. 546 U.S. at 62 ("the rule applies with equal effect ...").

K. Medtronic's "Coerced Royalties" Argument

Medtronic implies (at 40) that its royalty payments (the withheld royalties) were "coerced by threatened enforcement action." However, Medtronic wanted a license to shield itself from an injunction, damages, and willful infringement. Further, Medtronic wanted the license to extend to new products. Otherwise, the new products could be subjected to an injunction, damages, and willful infringement.

After obtaining this license and its important benefits, Medtronic seemingly now complains that its withheld royalty payments were "coerced." The term "coerced" usually implies wrongful coercion. There was no such wrongful act in the case at bar.

L. Medtronic's "Insurances Cases" Argument

Medtronic asserts (at 26-27) that the three insurance cases cited by the Federal Circuit do not support the Federal Circuit's decision. Medtronic is wrong.

As previously noted, in reviewing the burden issue, the first thing to do is to determine if only one party is seeking relief. If so, that party will have the burden.

In *Reliance Life Ins. Co. v. Burgess*, 112 F.2d 234 (8th Cir. 1940), only the insurance company (the plaintiff) sought relief. As noted by the Federal Circuit, the *Reliance* decision (*id.* at 237) stated that the insured "asked no affirmative relief [and] prayed only to be discharged with their costs." Pet. App. 13a. Accordingly, the plaintiff had the burden.

In both *American Eagle Ins. Co. v. Thompson*, 85 F.3d 327, 331 (8th Cir. 1996) and *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1175 (3d Cir. 1976), both the insurance company and the insured were seeking relief. Accordingly, the insured bore the burden in each instance since, as stated by the Federal Circuit, "[i]n insurance cases, courts generally place the burden on the party seeking recovery under a policy." Pet. App. 13a.

The case at bar is like *Reliance* because only one party (Medtronic) is seeking relief. The case at bar is not like *American Eagle* or *Fireman's* because, in each of those cases, both parties (the insurance company and the insured) were seeking relief.

M. Medtronic's "Finality" Argument

Medtronic's "finality" argument (at 31-34) was not presented to or considered by the Federal Circuit. Nor was it included in Medtronic's petition for certiorari. Accordingly, it should not be considered by this Court. *United Foods, supra*, 533 U.S. at 417.

Medtronic's "finality" argument is also baseless. There is no "finality" exception to the normal default rule. The rule is applicable even if there were some unusual situation where there might not be total finality.

Further, there is no difficulty with finality in the case at bar. Medtronic's argument appears to be that, if Mirowski does not have the burden, there will be no finality to the judgment. However, the 1991 license and the 2006 LTA provide that Mirowski is entitled to the withheld royalties (with interest) if Medtronic fails to prevail in its DJ action. Medtronic has not disputed this point.

There would also be finality in a *MedImmune*-type situation. If the licensee is unable to prove that its product is not covered, the licensee will either have to continue to pay the royalties or, if it does not, it can be sued for infringement.

IX. Subject Matter Jurisdiction is Present

A. *Gunn v. Minton*

Tessera's *amicus* brief is based upon this Court's decision earlier this year (February 20) in *Gunn v. Minton*, 133 S. Ct. 1059 (2013).

Gunn was a malpractice action against an attorney (Jerry Gunn) by his client (Vernon Minton) who asserted that Gunn's error in an infringement action, in which Gunn represented Minton, resulted in Minton having his patent held invalid.

Minton sued the accused infringers in a Texas federal court. The district court held the patent invalid under the on-sale bar of 35 U.S.C. §102 and the Federal Circuit affirmed. *Minton v. National Assn. of Securities Dealers, Inc.*, 226 F. Supp. 845, 873, 883-884 (E.D. Tex. 2002), *aff'd*, 336 F.3d 1373, 1379-80 (Fed. Cir. 2003).

Minton then filed his malpractice action against Gunn in a Texas state court, asserting that Gunn should have countered the on-sale bar with the experimental use exception to the on-sale bar. Gunn defended on the basis that Minton's supposed experimental use exception had no factual basis and, therefore, it was not malpractice not to have asserted it. The Texas trial court granted summary judgment to Gunn. *Gunn*, 133 S. Ct. at 1063.

On appeal to the Texas Court of Appeals, Minton raised a new argument, *i.e.*, since his action "was based on an alleged error in a patent case, it 'aris[es] under' federal patent law for purposes of 28 U.S.C. §1338(a)." Since §1338(a) provides exclusive federal jurisdiction, Minton argued that he had brought his case in a court that did not have subject matter jurisdiction and, therefore, his malpractice case had to be retried in federal court. *Id.*

The Texas Court of Appeals rejected this argument, holding that "the federal interests implicated by Minton's state law claim were not sufficiently substantial to trigger §1338(a) 'arising under' jurisdiction" and "finding exclusive federal jurisdiction over state malpractice actions would ... disturb the balance of federal and state judicial responsibilities." *Id.*

Minton appealed to the Supreme Court of Texas who agreed with Minton's lack of subject matter jurisdiction argument and, accordingly, reversed. *Id.*

Gunn appealed to this Court who reversed, holding that there was no federal jurisdiction even though Minton's malpractice claim depended upon a patent law question, *i.e.*, whether there was a factual basis for the experimental use exception to counter the on-sale bar used to invalidate Minton's patent. *Id.* at 1068-69.

This Court held that it is not sufficient for federal jurisdiction that Minton's malpractice claim depended upon the answer to a patent law question. Something more was needed, *i.e.*, even though the patent law question was "vitally important to the particular parties in [the] case," the answer to the question had to be "significant to the federal system as a whole." *Id.* at 1068.

Further, permitting federal jurisdiction for Minton's malpractice claim would disturb "the appropriate 'balance of federal and state judicial responsibilities,'" especially since "[t]he [s]tates ... have 'a special responsibility for maintaining standards among members of the licensed professions'" and "[t]heir 'interest ... in regulating lawyers is especially great since lawyers are essential to the primary governmental functions of administering justice, and have historically been officers of the courts.'" *Id.*

In addition, Minton's malpractice claim was "backward-looking" and "merely hypothetical" – "*If* Minton's lawyers had raised a timely experimental-use argument would the result in the patent infringement proceeding have been different?" *Id.* at 1066-67, emphasis by Court.

Thus, there is only federal subject matter jurisdiction if the patent law question (1) is part of a claim for patent infringement or (2) has significant "importance ... to the federal system as a whole."

B. Type-1 and Type-2 Subject Matter Jurisdiction

Tessera agrees that *Gunn* holds, as stated above, that there is only federal subject matter jurisdiction if the patent law question (1) is part of a claim for patent infringement or (2) has significant "importance ... to the federal system as a whole." Tessera characterizes (1) and (2) above as "Type-1" and "Type-2" jurisdiction respectively.

Most of Tessera's brief (1-27) asserts that the license dispute between Medtronic and Mirowski does not suffice for Type-1 jurisdiction. Mirowski, however, does not assert Type-1 jurisdiction, but does submit that type-2 jurisdiction is appropriate here.

Type-2 jurisdiction is directed to the patent law question having sufficient importance to the federal system as a whole. That the burden of proof issue in the case at bar has such sufficient importance to the federal system as a whole is apparent from the fact that this Court granted Medtronic's petition for certiorari. Also attesting to this importance, the Solicitor General filed an *amicus* brief and moved to participate in oral argument.

Further, the burden of proof issue in the case at bar (apart from the fact that the license and the LTA specify that Medtronic is to bring the DJ action if it wants relief from its license) is not restricted to the parties in this case but should, as Medtronic asserted in its petition, arise in almost every *MedImmune* type case in which the licensee seeks relief from its license.

Also, this burden of proof question in the case at bar is not a "backward-looking" or "hypothetical question" as was the case in *Gunn*. *Id.* The decision in this case will likely control the burden of proof on claim coverage in almost all future *MedImmune* type DJ actions.

In addition, the patent law issue in the case at bar does not involve important state issues such as "maintaining standards among members of the licensed professions" and "regulating lawyers ... since [they] are essential to the primary governmental function of administering justice" as was the case in *Gunn*. *Id.* at 1068. Thus, a decision that Type-2 jurisdiction is present in the case at bar will not disturb "the appropriate 'balance of federal and state judicial responsibilities.'" *Id.*

Tessera in its brief does not give appropriate weight to the above reasons for the presence of Type-2 Jurisdiction in the case at bar. The portion of Tessera's brief that concerns Type-2 jurisdiction is only four pages (27-31). In contrast, the portion directed to Type-1 jurisdiction is 27 pages (1-27). Most significantly, Tessera in its brief does not recognize that the standard for Type-2 jurisdiction mirrors the standard used by this Court in deciding whether to grant certiorari in a patent case.[32]

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[32] Supreme Court Rule 10 provides – "A petition for a writ of certiorari will be granted only for compelling reasons. The following ... indicate the character of the reasons the Court considers: ... (c) ... a United States court of appeals has decided an important question of federal law that has not been, but should be, settled by this Court ... ."

C. Subject Matter Jurisdiction in the Federal Circuit

Since Tessera asserts that there is no Type-1 or Type-2 jurisdiction, it asserts that the Federal Circuit did not have subject matter jurisdiction. Tessera asserts (at 31) that

> Consequently, the Federal Circuit's judgment should be vacated, and the case remanded with instructions to transfer the appeal to the Third Circuit pursuant to 28 U.S.C. §1631 to determine whether another jurisdictional basis in the district court, such as diversity, existed, and to decide the appeal on the merits if it did. *See Christianson*, 486 U.S. at 819.

Mirowski disagrees since Type-2 jurisdiction is present in the case at bar for the reasons noted above. However, if this Court disagrees, Mirowski agrees with Tessera that the case should be remanded to the Third Circuit under §1631 since there was 28 U.S.C. §1332 diversity of jurisdiction in the district court.

Tessera also asserts (at 32) that "vacatur and remand are appropriate because the burden of persuasion in this case may be governed by state, not federal, law." Mirowski disagrees. The LTA provides that it "shall be interpreted and construed, and the legal relations created herein shall be determined, in accordance with the laws of the State of Minnesota and the United States." Thus, the laws of the United

States should control. Further, it is not believed that the laws of Minnesota differ from the laws of the United States as to the burden of proof being allocated to the party seeking relief.

10. If It Is Determined That Mirowski Has the Burden, a Remand to the Federal Circuit is Necessary So That It Can Consider the District Court's Errors That Were Mooted By Its Burden of Proof Decision.

As noted *supra* in "The District Court Proceedings," the district court erroneously excluded Mirowski's claim coverage evidence on the basis that Mirowski's expert, Dr. Berger, supposedly did not include in his expert report an explanation of the presence of a "sense amplifier" in Medtronic's CRT products. In doing so, the district court erred for a number of reasons.

First, Dr. Berger's report did include the presence of the sense amplifier in Medtronic's CRT products. Second, most of the claims at issue in both the '119 and '897 patents did not recite a sense amplifier and, therefore, did not require its presence. Third, Medtronic's engineer Ms. Kleckner, who had helped to design its CRT products, testified at trial that Medtronic's devices did include the sense amplifier.

Fourth, Medtronic had limited the infringement issues through discovery so as not to include the presence of a sense amplifier. Fifth, wearing belt and suspenders, Mirowski proved claim coverage at trial despite the fact that it had no burden to do so. Dr.

Berger's testimony at trial (and his expert report) applied each element of each claim at issue including the sense amplifier to each Medtronic CRT product.

After the Federal Circuit determined that Medtronic, not Mirowski, had the burden on claim coverage, the above errors by the district court became moot and the Federal Circuit did not consider or even mention them.

Accordingly, if this Court were to determine that Mirowski had the burden on claim coverage, this case should be remanded to the Federal Circuit so that it can consider the district court's errors noted above that it did not consider in its decision.

CONCLUSION

For the foregoing reasons, the judgment of the Federal Circuit should be affirmed. If not, this action should be remanded to the Federal Circuit so that it can consider the district court's errors that were mooted by the Federal Circuit's decision that Medtronic had the burden on claim coverage.

This Court has subject matter jurisdiction. If not, this case should be remanded to the Federal Circuit with instructions to transfer the appeal to the Third Circuit pursuant to 28 U.S.C. §1631 to decide the appeal after determining the presence of diversity jurisdiction.

Respectfully submitted,

ARTHUR I. NEUSTADT
Counsel of Record
THOMAS J. FISHER
JOHN F. PRESPER
OBLON, SPIVAK, MCCLELLAND,
MAIER & NEUSTADT, LLP
1940 Duke Street
Alexandria, VA 22314
(703) 413-3000

SIDNEY J. SILVER
SILVER, FREEDMAN &
TAFF, LLP
3299 K Street, N.W.
Washington, D.C. 20007
(202) 295-4500

September 16, 2013

Counsel for Respondent
Mirowski Family Ventures, LLC

REPLY
BRIEF

RECORD
AND
BRIEFS

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Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR PETITIONER

MARTIN R. LUECK
Counsel of Record
JAN M. CONLIN
STACIE E. OBERTS
ROBINS, KAPLAN, MILLER & CIRESI LLP
2800 LaSalle Plaza
800 LaSalle Ave.
Minneapolis, MN 55402
(612) 349-8500
mrlueck@rkmc.com

SETH P. WAXMAN
PAUL R. Q. WOLFSON
BRIAN H. FLETCHER
CAROLYN JACOBS CHACHKIN
WEILI J. SHAW
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006

MARK C. FLEMING
WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109

Library of Congress
Law Library

RULE 29.6 STATEMENT

The Rule 29.6 statement included in Medtronic's opening brief remains correct.

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ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR PETITIONER

Medtronic's opening brief established two points that resolve this case: First, the burden of proof in a civil action is determined by the applicable substantive law, and that burden does not shift when a declaratory action inverts the parties' nominal status. Pet. Br. 18-31. Second, federal patent law places the burden on the patentee to prove that accused products infringe its patent. *Id.* 34-47. Together, these principles establish that, in a suit seeking a declaratory judgment of noninfringement, the burden of proof remains with the patentee. MFV identifies no reason to depart from that rule where—as in this case and in *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118 (2007)—the declaratory action is brought by a licensee.

Most of MFV's numerous arguments reduce to two propositions, both unsound. First, MFV asserts that this case is controlled by rote application of "the ordinary default rule" placing the burden of proof on the plaintiff. *Schaffer ex rel. Schaffer* v. *Weast*, 546 U.S. 49, 56 (2005). But as Medtronic demonstrated, *Schaffer's* "default rule" cannot be applied mechanically to declaratory actions. Rather, that rule helps determine how the relevant *substantive* law allocates the burden, and that allocation is not altered where, as here, the declaratory judgment procedure inverts the parties' nominal roles.

Second, MFV insists that this case is not about patent infringement, but "claim coverage." Yet MFV concedes (Br. 48) that Medtronic would have "subjected itself to a suit for infringement" had it refused to pay royalties on the accused products. Medtronic instead did what the parties envisioned and what *MedImmune* permits: It presented the infringement dispute in a declaratory action. Except for the remedy, the issues in this action are exactly the same as those that would have been presented in the infringement suit MFV would have brought had Medtronic refused to pay.

The remaining arguments raised by MFV and its amici lack merit, as does Tessera's objection to jurisdiction.

ARGUMENT

I. A DECLARATORY ACTION'S INVERSION OF PARTY STATUS DOES NOT SHIFT THE BURDEN OF PROOF

The Declaratory Judgment Act's reforms were "procedural only," *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 240 (1937), leaving "substantive rights unchanged," *Beacon Theatres, Inc.* v. *Westover*, 359 U.S.

500, 508-509 (1959). The burden of proof is one such right: It is "a part of the very substance of [the] claim and cannot be considered a mere incident of a form of procedure." *Garrett* v. *Moore-McCormack Co.*, 317 U.S. 239, 249 (1942). Thus, when a party invokes the Act to seek a declaration of non-liability, it does not assume the burden merely because it is the plaintiff. Instead, to preserve the parties' substantive rights, the burden must remain with the party that would have borne it had the same issue been litigated in a traditional coercive action.

MFV scarcely disputes these premises, yet it insists that, absent a counterclaim, the burden always lies with the declaratory judgment plaintiff. Resp. Br. 2 & n.1. This erroneous assertion underlies nearly every argument in MFV's brief. *See id.* 1-2, 25-28, 34-36, 46-47, 49, 50-51; *see also* IPO Br. 6-7, 12.

A. MFV rests entirely on *Schaffer's* observation that the burden of proof ordinarily lies with "'the plaintiff who generally seeks to change the present state of affairs.'" 546 U.S. at 56. But *Schaffer* did not address the allocation of the burden in inverted declaratory actions, where the plaintiff seeks a declaration of non-liability rather than a coercive judgment altering the status quo. Pet. Br. 28 & n.11. MFV also identifies no case applying *Schaffer* as it urges. In fact, *Schaffer's* "default rule" is a tool for determining where the relevant substantive law places the burden. *See* 546 U.S. at 56 ("[T]he touchstone of our inquiry is, of course, the statute."). And nothing in *Schaffer* suggests that this or any other aspect of the substantive law governing a dispute changes when that dispute comes before the court through the declaratory judgment procedure; indeed, this Court has repeatedly emphasized the contrary. Pet. Br. 18-23.

In this regard, *Schaffer's* default rule thus resembles the well-pleaded complaint rule and the test for the Seventh Amendment jury-trial right: The rule in an inverted declaratory action is based on the one that would have governed in the equivalent coercive suit brought by the declaratory judgment defendant. *See Franchise Tax Bd. of Cal.* v. *Construction Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 16 (1983); *Beacon Theatres*, 359 U.S. at 504; Pet. Br. 23-28.[1]

B. Medtronic and the United States offered several additional reasons to reject a rule that the plaintiff always bears the burden in an inverted declaratory action. Pet. Br. 23-34; U.S. Br. 18-23. MFV and its amici have no persuasive response.

First, MFV does not even cite, let alone distinguish, this Court's precedents holding that where the same parties could litigate a dispute through two procedures involving different party alignments, the burden should not depend on which party happens to be the plaintiff. Pet. Br. 24-25; *see Alaska Dep't of Envtl. Conservation* v. *EPA*, 540 U.S. 461, 493-494 (2004); *F. Vitelli & Son* v. *United States*, 250 U.S. 355, 358-359 (1919).

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[1] As the United States notes (Br. 20 n.6), this Court has stated that "it 'is not clear'" whether satisfaction of the well-pleaded complaint rule by the equivalent coercive action is *sufficient* to confer jurisdiction over an inverted declaratory action. *Textron Lycoming Reciprocating Engine Div., AVCO Corp.* v. *UAW*, 523 U.S. 653, 659 (1998); *but see ABB Inc.* v. *Cooper Indus., LLC*, 635 F.3d 1345, 1350-1351 (Fed. Cir. 2011) (answering the question left open in *Textron* in the affirmative). But the relevant point for this purpose is that the well-pleaded complaint rule cannot be applied mechanically to inverted declaratory actions. Instead, courts must look to the equivalent coercive suit, because satisfaction of the well-pleaded complaint rule by that hypothetical suit is at least a *necessary* condition for jurisdiction. *See Textron*, 523 U.S. at 658-659. (The question left open in *Textron* does not affect jurisdiction in this case, because both MFV's hypothetical infringement action and Medtronic's declaratory complaint satisfy the well-pleaded complaint rule. *See id.* at 659 n.4; *infra* n.12.)

Second, MFV all but ignores the great weight of precedent and commentary concluding that the burden of proof does not automatically lie with a plaintiff seeking a declaration of non-liability. Pet. Br. 25-27 & nn.9-10; U.S. Br. 19-21. Instead, MFV merely echoes the Federal Circuit's erroneous characterization of the three insurance cases cited in the opinion below. But both *American Eagle Insurance Co.* v. *Thompson*, 85 F.3d 327 (8th Cir. 1996), and *Fireman's Fund Insurance Co.* v. *Videfreeze Corp.*, 540 F.2d 1171 (3d Cir. 1976), placed the burden on the party that would have borne it in a coercive suit, even though that party (the insured) was the nominal defendant. MFV asserts (Br. 50) that in these cases both parties were "seeking relief." But there was no counterclaim in *American Eagle*, and the defendant in that case was thus "seeking relief" only in the sense that MFV seeks relief here: Prevailing in the suit would have established the insured's right to payment from the insurer, just as a victory by MFV would establish its right to funds currently held by Medtronic.[2] The same is true in numerous other cases placing the burden on the declaratory judgment defendant. Pet. Br. 26 & n.9 (citing cases).[3]

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[2] *Fireman's Fund* did involve a counterclaim, but the court did not suggest that its allocation of the burden would have changed had the counterclaim been absent. *See* 540 F.2d at 1176 ("The burden of proof which usually accompanies the affirmative of the issue of coverage should not be shifted merely due to the form of the action.").

Third, because the allocation of the burden of proof "frequently may be dispositive," *Lavine* v. *Milne*, 424 U.S. 577, 585 (1976), MFV's rule would attach a substantial penalty to invocation of the declaratory procedure by parties seeking to establish their nonliability—thereby undermining the usefulness of the Declaratory Judgment Act in one of the situations it was principally intended to address. Pet. Br. 4-7, 29-30.

Finally, MFV's argument would undermine the finality of declaratory judgments because an adverse result would not necessarily bind a plaintiff who failed to carry a burden it would not bear in a coercive suit raising the same issue. Pet. Br. 31-34. MFV asserts (Br. 51) that there is no problem with finality in cases of this type because, if a licensee loses a declaratory action yet refuses to pay royalties, "it can be sued for infringement." But that is exactly the problem: If MFV's position were correct, then the parties could be required to relitigate the same question under a different allocation of the burden in a future infringement action. MFV does not defend that illogical result.

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[3] MFV's third insurance case is *Reliance Life Insurance Co.* v. *Burgess*, 112 F.2d 234 (8th Cir. 1940). But MFV offers no response to Medtronic's showing that, to the extent *Burgess* can be read to assign the relevant burden to the plaintiff insurer at all, it did so because the disputed issue was "an affirmative defense" on which the insurer would have borne the burden even as the defendant in a coercive action. *American Eagle*, 85 F.3d at 331; *see* Pet. Br. 27 & n.10.

II. [illegible] Case Is Governed By The Patent Law's Requirement That The Patentee Prove Infringement

MFV and its amici do not dispute that federal patent law requires patentees to prove infringement. *Railroad Co.* v. *Mellon*, 104 U.S. 112, 119 (1881); *Cammeyer* v. *Newton*, 94 U.S. 225, 231 (1877).[4] Instead, they argue that the issue presented in this case is not really patent infringement, that the parties' agreements justify a different placement of the burden, and that requiring patentees to prove infringement in suits brought by licensees would undermine various policy goals. All of these objections are unsound.

A. The Issues In This Case Are Identical To Those In An Infringement Action

MFV claims that, because Medtronic is a licensee and does not face a coercive counterclaim for damages, it is "claim coverage and not infringement that is at issue here." Resp. Br. 26; *see also id.* 34-35, 47-48. That is both wrong and irrelevant.

1. MFV admits that, had Medtronic refused MFV's demand for royalties on Medtronic's newly developed products, Medtronic "would have subjected itself to a suit for infringement." Resp. Br. 48; *see also* JA13 (license allows termination for nonpayment of royalties); *MedImmune*, 549 U.S. at 122 (breaching licensee could face an "infringement action"). Like other "prospective defendants who sue to establish their

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[4] Contrary to MFV's assertion (Br. 21, 28), Medtronic has not "abandoned" its argument based on *Under Sea Industries, Inc.* v. *Dacor Corp.*, 833 F.2d 1551 (Fed. Cir. 1987); rather, Medtronic is simply relying on this Court's precedents establishing the same proposition—*Railroad Co.* and *Cammeyer*.

nonliability," *Beacon Theatres*, 359 U.S. at 504, Medtronic is seeking a declaration that MFV would not have prevailed in that threatened action.

Accordingly, even though a court could not find that Medtronic is *presently* infringing MFV's patents, the question presented is still one of patent infringement: The court must determine whether MFV *would* have prevailed in an infringement suit if Medtronic had refused to pay the demanded royalties. The same is often true when a party seeks a declaration regarding contemplated future conduct. For example, when "parties in dispute[] over their rights over a contract ... sue for a declaration of rights, without breach of the contract," S. Rep. No. 73-1005, at 2 (1934), the court cannot declare that one of the parties is *presently* in breach; instead, the question is whether the contemplated action *would* constitute a breach. But "the issue to be determined is essentially the same" whether the dispute is presented in a coercive action or a suit seeking a declaration of non-liability. *Aetna*, 300 U.S. at 244. Thus, actions seeking "declaratory judgments of invalidity or noninfringement" are "in substance ... infringement suit[s] with the parties initially reversed." 7 *Chisum on Patents* § 20.03[4][c][vi] n.460 (2011).

2. In any event, even if MFV were correct that the issue here is "claim coverage" rather than infringement, the distinction is purely semantic. Either way, the court must decide whether Medtronic's products practice every element of one of MFV's patent claims. Either way, the answer turns on federal patent law governing claim construction, literal infringement, the doctrine of equivalents, and other matters. And either way, the result will determine whether Medtronic must pay MFV. The only difference is that the amount at stake has been fixed by contract rather than by a ju-

ry verdict. *Accord* U.S. Br. 27-28. MFV fails to identify any reason why that difference in *remedy* should shift the burden regarding *liability*.

3. MFV also repeats (Br. 25-26, 37-38) the Federal Circuit's argument that declaratory judgment cases requiring the patentee to prove infringement are distinguishable because they involved infringement counterclaims. But those cases did *not* universally feature counterclaims.[5] In any event, neither the Federal Circuit nor MFV cited *any* authority, in *any* context, suggesting that the burden on a party's declaratory judgment claim should change depending on whether its *opponent* counterclaims. Instead, MFV relies entirely on its assertion that under *Schaffer*, the burden always rests on the plaintiff unless the defendant "seeks relief" by filing a counterclaim—an assertion that fails for the reasons discussed in Part I.[6]

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[5] *See, e.g.*, *United Sweetener USA, Inc.* v. *Nutrasweet Co.*, 760 F. Supp. 400, 408, 417 (D. Del. 1991) (placing burden on defendant patentee who did not counterclaim); *Zenith Labs., Inc.* v. *Bristol-Myers Squibb Co.*, 1992 WL 171910, at *1, *25, *32 (D.N.J. July 21, 1992) (same); *see also Larami Corp.* v. *Amron*, 1994 WL 369251, at *8 (S.D.N.Y. July 13, 1994) (same in trademark action).

[6] MFV and the opinion below sometimes suggest that the placement of the burden should turn on whether a counterclaim is *possible* rather than whether one is actually filed. Pet. App. 14a; Resp. Br. 37-38. But that rule finds no support even in MFV's erroneous reading of *Schaffer*, which would place the burden on parties that "seek relief"—not those that *could* seek relief. And MFV would not prevail under such a rule in any event, because nothing prevented it from filing a counterclaim seeking a declaratory judgment of infringement. *See* La Belle, *"Reverse" Patent Declaratory Judgment Actions: A Solution for* Medtronic, U. Penn. L. Rev. Online (forthcoming 2013), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2334476. Contrary to MFV's unexplained assertion (Br. 27), there is no Article III obstacle to such a declara-

B. The Parties' Agreements Provide No Reason To Shift The Burden

MFV and amicus IPO assert that Medtronic should bear the burden because it is seeking to reopen matters settled by the parties' agreements. But that argument mischaracterizes both the license and the Litigation Tolling Agreement, which expressly recognized the parties' patent disputes and contemplated litigation to resolve them.

1. Medtronic is not seeking "relief from its license" or a "better deal" than the one it negotiated. Resp. Br. 11, 23, 36-37, 39, 47, 55; IPO Br. 5-6. If Medtronic's products are found not to infringe, it has no royalty obligation under the license. For the same reason, Medtronic is not "challeng[ing] the express terms of the contract" (IPO Br. 12), but upholding them. There is no presumption that Medtronic's new products fall within the license or MFV's patents.

The parties certainly never intended that the license and LTA would "settle an infringement dispute" (Resp. Br. 24-25, 39-40), nor did they "fully negotiate[ ]" a "bargain" (IPO Br. 9-10) that MFV entered into "on the assumption that there will be no litigation costs" (*id.* 13). To the contrary, as even MFV recognizes (Br. 9-10), the license expressly contemplated litigation to resolve disputes over validity and infringement, and the LTA—the *Litigation* Tolling Agreement—acknowledged "an actual controversy" over patent validity and scope and was designed to facilitate litigation, not settle it. JA20; *see* JA23-28.

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tory counterclaim. So long as the licensee's action presented a justiciable controversy, *see MedImmune*, 549 U.S. at 127-128, a counterclaim presenting the same dispute would satisfy Article III as well.

2. Relatedly, MFV and IPO contend that making a licensor bear the burden it would bear in any other patent litigation discourages settlements. Resp. Br. 23, 39; IPO Br. 10, 13. MFV even posits (Br. 39-40) that an accused infringer could settle a dispute through a license, only to reopen it the next day. But such a scenario can be easily avoided; a contract designed to *settle* litigation could make royalty obligations independent from infringement, such as by requiring lump sum payments or payments for net sales on existing products. It could also provide for license termination if the licensee seeks to reopen issues resolved by the settlement. It might even be able to expressly bar the licensee from challenging infringement. *Cf. Baseload Energy, Inc.* v. *Roberts*, 619 F.3d 1357, 1361-1362 (Fed. Cir. 2010) ("[C]onsent decrees and settlement agreements may … provide for a patent license while barring challenges to patent invalidity and unenforceability.").

This case presents no such scenario. A license that merely requires royalty payments on infringing products cannot be said to "settle[]" a dispute in which the licensee claims that "the agreement does not call for royalties because their product does not infringe the patent." *MedImmune*, 549 U.S. at 134-135. Such an argument is even less credible here, where the parties' agreements expressly recognize their dispute and provide for its resolution through litigation.

3. IPO's remaining arguments seek to relitigate *MedImmune*. IPO's principal objection (Br. 12) is that a suit by a licensee may require a patentee to endure "protracted litigation" without the "potential statutory damages and remedies" available in infringement actions. But that describes every declaratory action under *MedImmune*, regardless of where the burden lies. And contrary to IPO's suggestion (Br. 8 n.6), *MedIm-*

mune clearly permits a licensee to challenge infringement, not merely validity and enforceability. *See* 549 U.S. at 137 (permitting licensees to seek a declaratory judgment "that the underlying patent is invalid, unenforceable, *or not infringed*" (emphasis added)).

4. Finally, there is no merit to MFV's claim (Br. 36-37) that the provisions of the license and LTA requiring Medtronic to bring the declaratory action amounted to an "agree[ment] that Medtronic would bear the burden."[7] As MFV's own amici recognize, the agreements nowhere addressed the burden or suggested that the parties intended an allocation different from that imposed by the patent law. IPO Br. 2 n.3; Philips Br. 4-5.[8] The fact that the agreements call for Medtronic to file the case simply gave Medtronic the option to agree to pay some or all of the royalties demanded, thus narrowing or obviating the litigation. And if anything, the parties' repeated use of variations on the word "infringe" indicates an intent that the lawsuit operate like standard infringement litigation. JA13, 23, 28; *accord* U.S. Br. 26-27 & n.11.

C. The Federal Circuit's Decision Is Inconsistent With Sound Patent Policy

1. MFV and its amici offer no persuasive response to the United States' observation that "the Federal

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[7] MFV made the same argument in opposing certiorari. Opp. 14. In granting review despite MFV's claim that the question presented is controlled by the particular contracts at issue, this Court "necessarily considered and rejected that contention." *United States* v. *Williams*, 504 U.S. 36, 40 (1992).

[8] The Court thus need not reach the question whether parties *could* contractually vary the burden of proof established by federal patent law. *Cf.* Philips Br. 4-7; Scholars Br. 22.

Circuit's burden-shifting rule would deter licensees' use of the declaratory-judgment mechanism, disserving the public interest in definitive judicial resolution of disputed issues of patent scope." U.S. Br. 30; *accord* Pet. Br. 45-47.

MFV first asserts (Br. 21-22, 28-29) that this argument was not raised below. But "parties are not limited to the precise arguments they made below." *Yee* v. *City of Escondido*, 503 U.S. 519, 534 (1992). Unlike *United States* v. *United Foods, Inc.*, 533 U.S. 405, 416-418 (2001), this case does not involve an attempt to raise a "new claim," but merely "a new argument to support what has been [Medtronic's] consistent claim," *Lebron* v. *National R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995).[9]

On the merits, MFV objects (Br. 31-34) to describing a patentee's rights as a "monopoly." *But see Blonder-Tongue Labs., Inc.* v. *University of Ill. Found.*, 402 U.S. 313, 344, 350 (1971) ("patent monopoly"). Semantics aside, however, neither MFV nor the authorities on which it relies deny the importance of the public interest in "full and free competition in the use of ideas which are in reality a part of the public domain," *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969). MFV also does not dispute that these policies are served by challenges to potentially overbroad patent claims as well as potentially invalid patents. *See Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996). MFV instead maintains (Br. 31) that these considerations are not implicated here because a licensee is already free to challenge the scope of the licensed patent in a declaratory action. But MFV cannot deny that the decision below *discourages* such suits—and thereby frustrates important patent policies—because it requires a licensee to shoulder a potentially outcome-determinative burden that would otherwise belong to the patentee. Pet. Br. 45-47; U.S. Br. 28-30; Scholars Br. 17-22.

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[9] MFV's other waiver assertions (Br. 41-45) fail for the same reason.

2. Medtronic also relied on the established principle that the burden should lie with "the party holding the affirmative of the issue," *Arthur* v. *Unkart*, 96 U.S. 118, 122 (1878), because of the difficulty of proving a negative. Pet. Br. 43-45; U.S. Br. 16-18. That difficulty is particularly acute in this context because patents often contain numerous claims, each of which might be infringed on a variety of theories.

MFV responds (Br. 42-43) that, because infringement requires proof that the accused device practices all elements of the asserted claims, "proving noninfringement is easier ... than proving infringement." But in *any* cause of action, the plaintiff seeking coercive relief must prove all elements of its claim, whereas the defendant need only negate one. Nonetheless, the law generally assigns the burden to the coercive plaintiff—including patentees suing for infringement—in part because it is easier and more efficient for a party to respond to a theory of liability than to anticipate and refute its opponent's potential theories in advance.[10]

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[10] MFV is correct (Br. 43-44) that courts grant summary judgment of noninfringement, but the summary judgment standard incorporates the substantive law's placement of the burden of proof. *See Celotex Corp.* v. *Catrett*, 477 U.S. 317, 322 (1986). The fact that parties receive summary judgment of noninfringement when they do *not* bear the burden thus says nothing about the difficulty of carrying a burden to *prove* noninfringement.

MFV argues that even if licensees bore the burden of proof, they would not be required to anticipate patentees' arguments. But MFV took the opposite position below, maintaining that "because they have no burden," MFV and its codefendants had "no obligation to set forth their contentions regarding their infringement assertions" before Medtronic provided its non-infringement contentions. JA37. MFV also maintained that the party with the burden should submit the first brief on the issue of infringement. Pet. App. 40a. District courts might be able to ameliorate these difficulties through case-management orders or local rules, but there is no requirement that they do so. The better, simpler, and doctrinally correct course is to preserve the allocation of the burden that applies in every other infringement action.

III. JURISDICTION IS PROPER

Amicus Tessera's challenge to jurisdiction is unfounded. The district court had jurisdiction under 28 U.S.C. § 1338(a)—and thus the Federal Circuit had jurisdiction under § 1295(a)(1)—because "federal patent law create[d] the cause of action" at issue. *Christianson* v. *Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988).[11] This case involves a cause of action for patent infringement under 35 U.S.C. § 271, and the fact that it is presented in "inverted" form as a declaratory action does not deprive the courts of jurisdiction. Tessera's contrary arguments—which would have meant that jurisdiction was lacking in *MedImmune* as well—are meritless.

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[11] Tessera labels this "Type 1" jurisdiction. MFV, in contrast, relies on what Tessera calls "Type 2" jurisdiction, which applies where state law creates the cause of action but the case necessarily presents a substantial question of federal patent law. *See Gunn* v. *Minton*, 133 S. Ct. 1059, 1064-1065 (2013). Medtronic agrees with MFV that the patent-law issues raised in suits like this one are more substantial than those found insufficient in *Gunn*, but the Court need not decide that question because this case involves a cause of action created by federal law.

1. Where a party seeks a declaration that it is not liable on a potential coercive claim, federal-question jurisdiction is determined by applying the well-pleaded complaint rule to the defendant's hypothetical coercive complaint raising the same issues. *See Franchise Tax Bd.*, 463 U.S. at 19. If that complaint would have arisen under federal law, there is also jurisdiction over the equivalent declaratory action. This much is common ground. Tessera Br. 6-7.

This suit arises under the federal patent laws because it seeks a declaration that Medtronic would not have been liable in an infringement action brought by MFV. *See supra* Part II.A. Medtronic's complaint recited MFV's assertion "that certain of Medtronic's [products] infringe" the patents-in-suit. JA40. And although the complaint described the parties' agreements, Medtronic sought only declarations that the patents-in-suit were invalid, unenforceable, and not infringed. JA45-46. Such an action arises under federal law: "[F]ederal courts have consistently adjudicated suits by alleged patent infringers to declare a patent invalid, on the theory that an infringement suit by the declaratory judgment defendant would raise a federal question." *Franchise Tax Bd.*, 463 U.S. at 19 n.19.[12]

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[12] Although there is a question whether jurisdiction lies where the "declaratory-judgment complaint rais[es] a *nonfederal* defense to an anticipated *federal* claim," *Textron*, 523 U.S. at 659; *see supra* n.1, there is unquestionably jurisdiction where, as here, an "alleged patent infringer[]" seeks "to declare a patent invalid"

2. Tessera makes three arguments against jurisdiction, all flawed.

First, Tessera asserts (Br. 18) that "the only coercive claim by MFV that can reasonably be said to have been anticipated, impending, or threatened as of the filing date of the initial complaint is a contractual one," not an infringement action. As *MedImmune* makes clear, however, the extent to which a coercive suit is "anticipated, impending, or threatened" relates to the existence of an Article III case or controversy in the declaratory action. *See* 549 U.S. at 132 n.11 (rejecting the rule that the declaratory plaintiff must have a "'reasonable apprehension of suit'" to establish standing). Tessera's objection thus amounts to a claim that the only justiciable controversy presented here is a state-law breach-of-contract claim, not an infringement action. But that is simply wrong: As in *MedImmune*, MFV asserted that Medtronic's products "infringe[d]" its patents (JA30), and—as MFV itself confirms (Br. 48)—if Medtronic had not paid "it would have subjected itself to a suit for infringement."

Tessera's only basis for claiming that an infringement action by MFV was not "anticipated, impending, or threatened" is that (according to Tessera) there was "no chance that Medtronic suddenly would abandon the contractual dispute resolution procedure ... by ceasing to pay royalties." Tessera Br. 18-19. But that argument is foreclosed by *MedImmune*. There, too, the licensee preferred to pay royalties rather than risk an infringement action. 549 U.S. at 122. And there, too, the licensee's payments rendered the threat of an in-

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or not infringed, *Textron*, 523 U.S. at 660 n.4. The defenses raised in such declaratory complaints—invalidity, unenforceability, and noninfringement—"themselves raise a federal question." *Id.*

fringement suit "remote, if not nonexistent." *Id.* at 128. But this Court held that there was nonetheless a justiciable controversy because those payments were coerced by the threat of an infringement suit. *Id.* at 132-134. The same is true here: Although Tessera notes that various features of the parties' agreements made it preferable for Medtronic to vindicate its rights through this declaratory action rather than risking an infringement suit, the relevant point is that if Medtronic *had* refused MFV's demands for payment, it would have faced an infringement action—a point that Tessera does not and could not deny.[13]

The cases on which Tessera relies are not to the contrary. As Tessera's citations indicate (Br. 16 & n.19), most of them found that a licensee's declaratory action *did* present a justiciable case or controversy arising under the patent laws. Tessera identifies only three cases that declined to allow a licensee to anticipate an infringement action. Two of them are no longer good law because—like the decision reversed in *MedImmune*—they held that the continuing existence of a license barred a declaratory action because it precluded an infringement suit. *See Milprint, Inc.* v. *Curwood, Inc.*, 562 F.2d 418, 420-422 (7th Cir. 1977) (finding jurisdiction lacking because "the existence of the license precludes the possibility of infringement"); *Thiokol Chem. Corp.* v. *Burlington Indus., Inc.*, 448 F.2d 1328, 1330-1331 (3d Cir. 1971) (allowing a separate declaratory action brought after termination of the license to proceed). Tessera's third case did not even decide an issue of jurisdiction, but rather upheld a district court's *discretionary* decision declining to hear a declaratory action. *See Product Eng'g & Mfg., Inc.* v. *Barnes*, 424 F.2d 42, 45 (10th Cir. 1970).

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[13] Tessera's argument also proves far too much. So long as Medtronic was paying royalties into a set-aside account in compliance with the license and LTA, MFV could not sue for breach of contract any more than it could sue for infringement. On Tessera's logic, therefore, no state-law claim was "anticipated, impending, or threatened" either. (Tessera speculates (Br. 18) that MFV could have filed a contract action to require Medtronic to make payments directly to MFV rather than into a set-aside account, but the LTA expressly provides for the payment of disputed royalties into the set-aside account. JA27-28.)

Second, Tessera argues (Br. 21-23) that even if Medtronic did face an infringement action, there is no federal-question jurisdiction because, had Medtronic refused to pay royalties, MFV could *also* have brought a state-law breach-of-contract claim.

This argument is well wide of the mark. Tessera relies on *Franchise Tax Board*'s observation that "[f]ederal courts have regularly taken original jurisdiction over declaratory judgment suits in which, if the declaratory judgment defendant brought a coercive action to enforce its rights, that suit would necessarily present a federal question." 463 U.S. at 19. But Tessera does not cite a single case interpreting this statement as *excluding* jurisdiction if the opponent could *also* raise potential state-law claims. As Tessera admits (Br. 23 n.22), numerous courts have rejected this view. *See Household Bank* v. *JFS Group*, 320 F.3d 1249, 1258-1259 (11th Cir. 2003) (citing decisions from seven other circuits).[14]

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[14] Neither *Holmes Group, Inc.* v. *Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002), nor *La Chemise Lacoste* v. *Alligator Co.*, 506 F.2d 339 (3d Cir. 1974), supports Tessera's argument. The plaintiff in *Holmes* did not seek a declaration regarding patent rights—patent issues entered the case only in a counterclaim. *See* 535 U.S. at 830. Contrary to Tessera's suggestion,

Third, Tessera argues (Br. 24-26) that the district court lacked jurisdiction because MFV's patents expired a few days before Medtronic filed its second amended complaint, meaning that when the operative complaint was filed Medtronic did not face the prospect of an infringement suit. That argument is likewise mistaken.

Statutory jurisdiction and Article III standing are generally determined at the time the suit is filed. *See Rockwell Int'l Corp.* v. *United States*, 549 U.S. 457, 473 (2007) ("[S]ubject-matter jurisdiction 'depends on the state of things at the time of the action brought.'"); *Davis* v. *FEC*, 554 U.S. 724, 734 (2008) ("[T]he standing inquiry remains focused on whether the party invoking jurisdiction had the requisite stake in the outcome when the suit was filed."). When a plaintiff amends its complaint, the *allegations* in the amended complaint supersede those in the original complaint, but the question remains whether the amended allegations demonstrate jurisdiction when the *original* complaint was filed. *See Rockwell*, 549 U.S. at 473 ("The state of things and the originally alleged state of things are not synonymous; demonstration that the original allega-

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therefore, the Court's statement that "the declaratory 'complaint did not assert any claim arising under federal patent law'" was not based on an obscure and unstated interpretation of *Franchise Tax Board*, but rather the fact that the declaratory complaint literally did not raise *any patent issue at all*. And *La Chemise Lacoste* did not hold that the mere *possibility* of a state-law claim defeated federal jurisdiction; rather, it found that the declaratory complaint did not specifically seek to anticipate a federal claim and that it was not clear that the defendant's threatened suit would have relied on federal law. *See* 506 F.2d at 345-346. Here, in contrast, Medtronic's complaint expressly sought to anticipate an infringement action and—as MFV itself confirms (Br. 48)—Medtronic would have been sued for infringement had it refused payment.

tions were false will defeat jurisdiction."); *Southern Utah Wilderness Alliance* v. *Palma*, 707 F.3d 1143, 1153 (10th Cir. 2013) (examining "the allegations in [the plaintiff's] Amended Complaint" to determine "whether [the plaintiff] had standing when the original complaint was filed"). Accordingly, expiration of MFV's patents after this suit was filed did not affect either jurisdiction under § 1338(a) or Medtronic's standing.

Of course, "an 'actual controversy' must exist not only 'at the time the complaint is filed,' but through 'all stages' of the litigation." *Already, LLC* v. *Nike, Inc.*, 133 S. Ct. 721, 726 (2013). But even if Tessera were correct that expiration of the patents precluded any possible new infringement suit by MFV,[15] this action plainly is not moot. The parties entered into a "Litigation *Tolling* Agreement" years before the patents expired. JA19, 29. At the time, Medtronic was not paying royalties on the products at issue here and MFV believed that those products infringed its patents; the LTA thus acknowledged "an actual controversy … under 35 U.S.C. § 271." JA20. The parties agreed that they would resolve that infringement dispute through this declaratory action and further agreed that Medtronic would maintain a specified amount in a set-aside account to be paid over to MFV if MFV prevails. JA28.

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[15] That assumption is debatable. Medtronic believes that it has complied with the parties' agreements and so is not liable for infringement, but—particularly if Medtronic simply refused payment rather than continuing to pursue this declaratory action—MFV could well attempt to assert that some pre-expiration action by Medtronic constituted a breach and seek infringement damages on that basis. *Cf. Hydril Co.* v. *Grant Prideco LP*, 474 F.3d 1344, 1351-1353 (Fed. Cir. 2007) (patentee asserted that a breach terminated the license and that the licensee was liable for infringement for post-breach use of the patented device).

Those funds now total more than $120 million and their disposition turns on the outcome of this suit.

These agreements in the LTA neither eliminated the Article III controversy nor changed the action into something other than one arising under the patent laws. Parties can liquidate damages by agreeing to make specified payments depending on the courts' liability determination. *See Nixon* v. *Fitzgerald*, 457 U.S. 731, 743-744 (1982); *Havens Realty Corp.* v. *Coleman*, 455 U.S. 363, 370-371 (1982). And an infringement action arises under the patent laws even if the parties have agreed to a license fixing the measure of infringement damages at the license royalty rate. *See Healy* v. *Sea Gull Specialty Co.*, 237 U.S. 479, 480-481 (1915) (Holmes, J.) (arising-under jurisdiction "was not affected by the fact that the plaintiffs relied upon a contract in fixing the mode of estimating damages").

The lower courts therefore properly exercised jurisdiction over this case under Article III and 28 U.S.C. §§ 1338(a) and 1295(a)(1).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

MARTIN R. LUECK
Counsel of Record
JAN M. CONLIN
STACIE E. OBERTS
ROBINS, KAPLAN, MILLER
& CIRESI LLP
2800 LaSalle Plaza
800 LaSalle Ave.
Minneapolis, MN 55402
(612) 349-8500
mrlueck@rkmc.com

SETH P. WAXMAN
PAUL R. Q. WOLFSON
BRIAN H. FLETCHER
CAROLYN JACOBS CHACHKIN
WEILI J. SHAW
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006

MARK C. FLEMING
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109

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AMICUS
CURIAE
BRIEF

No. 12-1128

In the Supreme Court of the United States

MEDTRONIC INC., PETITIONER

v.

BOSTON SCIENTIFIC CORPORATION, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

DONALD B. VERRILLI, JR.
Solicitor General
Counsel of Record
STUART F. DELERY
Acting Assistant Attorney General
MALCOLM L. STEWART
Deputy Solicitor General
CURTIS E. GANNON
Assistant to the Solicitor General
SCOTT R. MCINTOSH
DANIEL TENNY
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

BERNARD J. KNIGHT, JR.
General Counsel
NATHAN K. KELLEY
Deputy Solicitor
MICHAEL S. FORMAN
WILLIAM LAMARCA
Associate Solicitors
United States Patent and Trademark Office
Alexandria, Va. 22313

QUESTION PRESENTED

Whether the burden of proof regarding patent infringement shifts from a patent holder to its licensee when the licensee sues the patent holder for a declaratory judgment that the licensee is not obligated to make royalty payments under the license because its products do not practice the patent.

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In the Supreme Court of the United States

No. 12-1128

MEDTRONIC INC., PETITIONER

v.

BOSTON SCIENTIFIC CORPORATION, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

INTEREST OF THE UNITED STATES

This case presents a question regarding the allocation of the burden of proof in a declaratory-judgment action in which a licensee seeks a declaration that royalties are not owed under a patent licensing agreement because the licensee's product does not practice the licensed patent. The United States Patent and Trademark Office (PTO) is responsible for "the granting and issuing of patents," 35 U.S.C. 2(a)(1), as well as for advising the President on domestic and international issues of patent policy and advising federal departments and agencies on matters of intellectual-property policy, 35 U.S.C. 2(b)(8) and (9). Several federal agencies are extensively engaged in the licensing of patented inventions to private entities, and the United States is also a licensee of various patents. The government accordingly has a substantial interest in this Court's resolution of the question presented.

STATEMENT

1. Under the federal Declaratory Judgment Act, ch. 512, 48 Stat. 955, a court of the United States is authorized, "[i]n a case of actual controversy within its jurisdiction" and "upon the filing of an appropriate pleading," to "declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. 2201(a); see Fed. R. Civ. P. 57. A principal purpose of that procedural mechanism is "to afford one threatened with liability an early adjudication without waiting until an adversary should see fit to begin an action after the damage has accrued." 10B Charles Alan Wright et al., *Federal Practice and Procedure* § 2751, at 457 (3d ed. 1998). The potential availability of declaratory relief enables the declaratory-judgment plaintiff "to minimize the danger of avoidable loss and the unnecessary accrual of damages." *Ibid.*; see S. Rep. No. 1005, 73d Cong., 2d Sess. 2-3 (1934).

When disagreements arise concerning the scope or validity of an issued patent, the Declaratory Judgment Act enables a party who has been "charged with infringement of [a] patent" to establish an actual controversy with the patentee and "seek a declaratory judgment, even if the patentee has not filed an infringement action." *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 95-96 (1993). Declaratory-judgment actions are "frequently" brought in the patent context, where they are recognized as being "useful to establish the rights of licensees and other interested persons." 10B *Federal Practice and Procedure* § 2761, at 572. Such actions "most common[ly]" take the form of "a suit by one thought to be an infringer for a declaration that he is not infringing the patent or that the patent is invalid." *Id.* at 572-573; see 12 James Wm. Moore et al., *Moore's Federal Practice* § 57.83[1], at 57-148 (3d ed. 2013).

2. The dispute in this case involves two patents that are owned by respondent Mirowski Family Ventures, LLC (Mirowski or respondent), and exclusively licensed to Guidant Corporation (which is a subsidiary of Boston Scientific Corporation). Pet. App. 2a, 22a.[1] The patents relate to "cardiac resynchronization therapy" devices, which stimulate portions of a patient's heart to ensure that the chambers of the heart are working in a coordinated way. *Id.* at 29a.

In 1991, petitioner Medtronic entered into a cross-licensing agreement with Guidant's predecessor-in-interest, Eli Lilly & Co. See J.A. 7-18. That agreement granted Medtronic a sublicense as to certain patents owned by Mirowski (including subsequently reissued patents), under which Medtronic agreed to pay royalties for practicing the patents. J.A. 12. The agreement also established a structured process for identifying and resolving disputes about Medtronic's obligations to pay royalties under that sublicense. J.A. 13-14. If Lilly or Mirowski believed that any new Medtronic device "infringe[d]" a covered patent, Lilly was to "notify Medtronic of such infringement," triggering a 90-day period to cure nonpayment of royalties or risk having the sublicense terminated. J.A. 13. If Medtronic chose to pay the royalty, it still retained "the right to challenge the validity and enforceability of [certain] patent[s] under the Mirowski license" and "the right to challenge Lilly's assertion of infringement of any of the Mirowski patents through a Declaratory Judgment action." *Ibid.*

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[1] Although Boston Scientific and Guidant are listed as respondents in the caption in this Court, they were not parties to the appeal below (Pet. App. 1a) and did not file a brief in this Court at the certiorari stage. Accordingly, this brief uses the term "respondent" to refer to Mirowski Family Ventures.

In 2003, a patent covered by the sublicense was issued, followed shortly by litigation in which Medtronic challenged the patent's enforceability and validity. Pet. App. 23a. In 2006, Medtronic, Guidant, and Mirowski entered into a litigation tolling agreement, J.A. 19-29, which acknowledged the parties' dispute about "the scope, validity and enforceability" of the patent, J.A. 20, and again provided a process under which Guidant or Mirowski "may notify Medtronic" of any claims in the patent "that Guidant or Mirowski asserts are infringed by [Medtronic products]." J.A. 23-24. Upon a "timely written notice of infringement," Medtronic would be permitted to initiate the "Final [Declaratory Judgment] Action challenging infringement, unenforceability and/or validity of the asserted claims of the [patents]." J.A. 24. Medtronic was required to "accumulate disputed royalties and future disputed royalties" in an escrow account. J.A. 27. After the conclusion of the declaratory-judgment action, Medtronic would be required to "cause distribution of the total amount in the [escrow] account to Mirowski or to Medtronic in a manner consistent with the [declaratory-judgment] decision." J.A. 28.

In October 2007, Mirowski's counsel, acting pursuant to the tolling agreement, "provide[d] notice" of Mirowski's contention that seven Medtronic products "infringe at least one of" 12 specified claims of the patent that had been issued in 2003. J.A. 30-31. A few weeks later, another patent issued, Pet. App. 30a, and Mirowski's counsel provided an amended notice, contending that the seven Medtronic products "infringe at least one of" four claims of the first patent and 25 claims of the second patent. J.A. 32-33.

3. a. As the parties' licensing arrangement contemplated, Medtronic responded to the notice of infringement by filing this declaratory-judgment action in the United States District Court for the District of Delaware, seeking a determination that its devices do not infringe the two patents and that the asserted claims of the two patents are invalid and unenforceable. J.A. 40-46. With respect to the noninfringement counts, Mirowski's answer to the declaratory-judgment complaint "admit[ted] that [Mirowski] has asserted" that several Medtronic devices "infringe at least one of" several claims in the two patents (though its answer identified a different set of infringed claims than had its two prior letters). J.A. 48-49.

In the district court, petitioner and respondent disagreed about who bore the burden of proving infringement at trial. Pet. App. 39a; J.A. 37-38. Petitioner contended that the burden remained on respondent, as the patent holder, while respondent contended that the burden of proof was on petitioner, as the plaintiff in the declaratory-judgment action. Pet. App. 39a-40a.

b. After a bench trial and post-trial briefing, the district court held, as relevant here, that, although respondent was the defendant in the declaratory-judgment action, it was the "part[y] asserting infringement" and therefore bore "the burden of proof by a preponderance of the evidence." Pet. App. 41a. The court's discussion of the burden-of-proof question relied on several Federal Circuit precedents, which had endorsed the proposition that "[t]he burden is always on the patentee to show infringement." *Id.* at 40a (citation omitted).

Applying that burden of proof to the evidence before it, the district court found that respondent's expert report lacked a "sufficient foundation" because respondent had failed to demonstrate that its expert had "considered each limitation of each asserted claim in comparison to each accused product before rendering his infringement opinions." Pet. App. 49a. The court held that respondent had failed to meet its burden of proving infringement by a preponderance of the evidence. *Id.* at 49a-52a. The district court also held that petitioner had failed to prove by clear and convincing evidence that the patent claims are invalid or unenforceable. *Id.* at 52a-83a; see *Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238, 2244-2252 (2011) (holding that, in order to prevail on an invalidity defense, the defendant in a patent-infringement suit must establish the invalidity of the patent by clear and convincing evidence). The court accordingly entered declaratory judgment in favor of petitioner "as to noninfringement" and declaratory judgment in favor of respondent (and its licensees) as to the "validity and enforceability" of the patents. J.A. 3.

4. Respondent appealed, petitioner cross-appealed, and the Federal Circuit vacated and remanded. Pet. App. 1a-18a. As relevant here, the court held that the district court had erred in placing the burden of proof with respect to infringement on respondent. *Id.* at 15a.

The court of appeals acknowledged that "a patentee who files a complaint or counterclaim alleging patent infringement bears the burden of proving that infringement." Pet. App. 10a (citing *Under Sea Indus.* v. *Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987)). The court also acknowledged that, when infringement claims are asserted as mandatory counterclaims in declaratory-judgment actions brought by accused infringers, "[t]he substantive burden of proof normally does not shift simply because the party seeking relief is a counterclaiming defendant in a declaratory judgment action." *Ibid.* (citing *Vivid Techs., Inc.* v. *American Sci. & Eng'g, Inc.*, 200 F.3d 795, 802 (Fed. Cir. 1999); *In re Technology Licensing Corp.*, 423 F.3d 1286, 1288-1289 (Fed. Cir. 2005), cert. denied, 547 U.S. 1178 (2006)).

The court of appeals held, however, that when the declaratory-judgment plaintiff is a licensee, the burden of proof regarding infringement (or the absence thereof) should shift from the patent holder to the licensee. The court stated that the question regarding the burden of proof in such a case "arises as a consequence of the Supreme Court's decision in *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118 (2007)." Pet. App. 8a. In *MedImmune*, this Court "found declaratory judgment jurisdiction notwithstanding the fact that the declaratory judgment plaintiff licensee continued to make royalty payments pursuant to a license." *Id.* at 8a-9a. The court of appeals viewed this case as involving "the proper allocation of the burden of persuasion in the post-*MedImmune* world," in a case where "a declaratory judgment plaintiff licensee seeks a judicial decree absolving it of its responsibilities under its license while at the same time the declaratory judgment defendant is foreclosed from counterclaiming for infringement by the continued existence of that license." *Id.* at 9a.

The court of appeals held that, "in the limited circumstance when an infringement counterclaim by a patentee is foreclosed by the continued existence of a license, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion." Pet. App. 14a. In reaching that conclusion, the court observed that, as a general matter, "the party seeking relief [from a court] bears the burden of proving the allegations in his complaint." *Id.* at 9a (citing *Schaffer* v. *Weast*, 546 U.S. 49, 56-57 (2005)). The court stated that, in this case, petitioner "is unquestionably the party now requesting relief from the court: it already has a license; it cannot be sued for infringement; it is paying money into escrow; and it wants to stop." *Id.* at 12a.

The court of appeals described respondent, by contrast, as "seek[ing] nothing more than to be discharged from the suit and be permitted to continue the quiet enjoyment of its contract." Pet. App. 12a. The court concluded that, because petitioner "is asking the court to disturb the status quo ante and to relieve it from a royalty obligation it believes it does not bear," petitioner "must present evidence showing that it is entitled to such relief." *Id.* at 13a. The court stated that, if the rule were otherwise, licensees would be "allow[ed] * * * to use *MedImmune's* shield as a sword—haling licensors into court and forcing them to assert and prove what had already been resolved by license." *Id.* at 14a.

The court of appeals vacated the declaratory judgment of noninfringement and remanded the case for further proceedings, in which the district court might exercise its discretion to permit petitioner to make "additional noninfringement contentions" in light of its burden of proof. Pet. App. 15a.[2]

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[2] The court of appeals also held, on petitioner's cross-appeal, that "the district court erred by restricting the claimed invention to the treatment of congestive heart failure." Pet. App. 18a. The court of appeals vacated the district court's determination with respect to validity, and it remanded to allow petitioner to "press its invalidity contention based upon the correct claim construction." *Ibid.* Those aspects of the court of appeals' decision are beyond the scope of the

SUMMARY OF ARGUMENT

A. It is well established that, although an issued patent is presumed valid, and an accused infringer must prove invalidity by clear and convincing evidence, the patent holder in an infringement suit bears the burden of proving that the accused product infringes the patent. Before the decision below, courts had consistently held that the burden of proving infringement remains with the patent holder even in a declaratory-judgment action initiated by the accused infringer. That allocation of the burden of proof is justified in part by the fact that a single patent may contain many claims, and there may be more than one potential rationale for asserting that a particular product infringes a particular claim. It would be unwieldy to require the alleged infringer to anticipate and negate every potential theory of infringement that the patent holder might assert.

B. The court of appeals held that the burden of disproving patent coverage should shift to petitioner because petitioner had initiated this declaratory-judgment action and respondent had not counterclaimed for infringement. That reasoning was erroneous. Although the plaintiff typically bears the burden of proof on the essential elements of its claims, that rule is subject to exceptions. Where, as here, the injury that a declaratory-judgment suit seeks to prevent is the imposition of legal liability in alternative proceedings that might otherwise be instituted by the declaratory-judgment defendant, the Declaratory Judgment Act allows the court to determine how the correlative enforcement suit would

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questions presented in this case, but are implicated by the petition for a writ of certiorari in *Mirowski Family Ventures, LLC* v. *Medtronic, Inc.*, No. 12-1116 (filed Mar. 14, 2013), which is currently pending before this Court.

be resolved, without requiring the declaratory-judgment plaintiff to expose itself to potential retrospective liability as a precondition to judicial resolution. When the declaratory-judgment mechanism is used in that manner, it is generally appropriate to apply the same burdens of proof that would govern in those alternative enforcement proceedings.

That approach reflects the procedural character of the Declaratory Judgment Act and the purposes the statute is intended to serve in this context. In order to determine how an infringement suit filed by a patent holder would have been resolved, the declaratory-judgment court must conduct the same factual inquiries, and apply the same body of law, that the court in an infringement suit would conduct and apply. The allocation of burdens of proof is a matter of substantive law, and there is no sound reason that a putative infringer's use of the declaratory-judgment mechanism should, without more, trigger a different allocation. That is particularly so because the practical justifications for requiring the patent holder to prove infringement apply equally in the declaratory-judgment context.

C. Contrary to the Federal Circuit's conclusion, the licensing arrangement between the parties here provides no sound basis for requiring petitioner to disprove patent coverage. The arrangement recognizes that disputes concerning patent coverage may arise, and it establishes a structured mechanism, culminating if necessary in a declaratory-judgment action filed by petitioner, for resolving those disputes. Nothing in the licensing and tolling agreements suggests that the parties intended the courts in such suits to do anything other than apply the same legal rules that would govern a similar declaratory-judgment action between parties with no prior course of dealing.

Besides being untethered to the terms of the parties' license and tolling agreements, the court of appeals' approach would deter licensees' use of the declaratory-judgment mechanism and would disserve sound patent policy. The Declaratory Judgment Act alleviates the dilemma that one in petitioner's position might otherwise face, between forgoing conduct it believes to be lawful and risking onerous retrospective penalties. The statute cannot fully vindicate that purpose if licensees who file declaratory-judgment suits must litigate questions of patent coverage on terms less favorable than defendants in infringement actions. And by deterring use of the declaratory-judgment mechanism to resolve disputed questions of patent scope, the court of appeals' approach would impede the public interest in prompt and dispositive judicial resolution of such issues.

ARGUMENT

A PATENT HOLDER BEARS THE BURDEN OF PROVING INFRINGEMENT OF ITS PATENT IN AN ACTION FOR A DECLARATORY JUDGMENT OF NONINFRINGEMENT BROUGHT BY A PATENT LICENSEE

The parties in this case disagree about whether some of petitioner's devices practice respondent's patents and therefore trigger petitioner's obligation to pay royalties under the terms of their license. Because infringement of a patent occurs when the patent is practiced "without authority" from the patent holder, 35 U.S.C. 271(a), and petitioner has been authorized to practice the patents at issue here so long as it fulfills its obligations under the licensing and tolling agreements, a judicial determination that petitioner's devices practice the patent would not subject petitioner to the remedies (including injunctive relief and treble damages, see 35 U.S.C. 283, 284) that the Patent Act authorizes in suits for infringement. See generally 35 U.S.C. 281-285. The parties' agreements nevertheless establish a structured dispute-resolution process, potentially culminating in a declaratory-judgment action filed by petitioner, that is triggered by respondent's assertion that some of petitioner's products "infringe" respondent's patents. The parties' evident intent was to allow a court to determine whether the manufacture and sale of petitioner's devices *would infringe* the patents if petitioner did not pay royalties it believes it does not owe.

The court of appeals recognized that, in almost every context, a patent holder has the burden of proof (*i.e.*, the burden of persuasion) with respect to whether its patent is infringed.[3] The court nevertheless concluded that, in the context of an action brought by a licensee for a declaration of noninfringement, that burden of proof should be imposed on the licensee. That result is not supported by the Declaratory Judgment Act, which (as applied to cases like this one) simply furnishes a procedural mechanism for securing a conclusive judicial resolution of the same legal issue that could arise in a different procedural posture. Nor is the altered burden of proof justified by the presence of a license (either in general or in this case). Petitioner's exercise of its right to employ the declaratory-judgment mechanism to clarify its rights and responsibilities, as contemplated by the license and authorized in *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118 (2007), should not come at the cost of assuming the burden of proof on the issue of infringement, which falls on the patent holder in every other context.

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[3] This Court has often observed that the phrase "burden of proof" has been used to mean different things. See, *e.g.*, *Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 n.4 (2011); *Schaffer* v. *Weast*, 546 U.S. 49, 56 (2005). As relevant here, it means the "burden of persuasion," which specifies "which party loses if the evidence is balanced." *Microsoft*, 131 S. Ct. at 2245 n.4. See Pet. App. 14a (equating "burden of proof" with "burden of persuasion"); Pet. Br. 12 n.5; Br. in Opp. 25-26.

A. The Burden of Proving Patent Infringement Generally Rests With The Patent Holder

1. As the court of appeals recognized, "[i]t is, of course, well settled that a patentee who files a complaint or counterclaim alleging patent infringement bears the burden of proving that infringement." Pet. App. 10a. This Court explained long ago that patent "[i]nfringement must * * * be shown by satisfactory proof; it cannot be presumed." *Railroad Co.* v. *Mellon*, 104 U.S. 112, 119 (1881).

In that regard, the question of infringement differs from another recurring issue in patent litigation: the question of patent validity. Congress has codified a presumption of validity for a patent that has been issued by the PTO. See 35 U.S.C. 282. Congress has "explicitly specifie[d]," moreover, that "the burden of proof" on that question is to be borne by the party who asserts the *in*validity of an issued patent and attempts to overcome the statutory presumption. *Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 (2011); see *id.* at 2242 (holding that invalidity must "be proved by clear and convincing evidence"); 35 U.S.C. 282 ("The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity."). With respect to infringement, by contrast, Congress has not enacted any similar presumption, but instead has left in place the established rule that the party asserting infringement bears the burden of proving it.[4]

Based on this Court's holding that "the burden to prove infringement never shifts [to the alleged infringer] if the charge is denied in the plea or answer," *Imhaeuser* v. *Buerk*, 101 U.S. 647, 662 (1880), it had been universally understood—until the exception created by the decision below—that "the burden of proof on factual issues relating to infringement rests upon the patent owner." 5B Donald S. Chisum, *Chisum on Patents* § 18.06[1][a], at 18-1180 (2007). As the Federal Circuit explained in 2008: "Neither [the patentee's] burden to prove infringement nor [the accused infringer's] burden to prove invalidity, both ultimate burdens of persuasion, ever shifts to the other party[.]" *Technology Licensing Corp.* v. *Videotek, Inc.*, 545 F.3d 1316, 1327; see, *e.g.*, *Under Sea Indus.* v. *Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) ("The burden always is on the patentee to show infringement.").[5]

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[4] Under 35 U.S.C. 295, there is a rebuttable presumption that a product was made from a process patented in the United States when the court finds a "substantial likelihood" that it was made in that way and the patent holder has, despite "a reasonable effort," been unable to "determine the process actually used in the production of the product." See Pet. Br. 37-38. Section 295 might be viewed as establishing a rebuttable presumption of infringement in certain narrow circumstances once a predicate showing has been made. Section 295 is not at issue in this case.

[5] Congress has included "[n]oninfringement, absence of liability" in a list of "defenses in any action involving the validity or infringement of a patent [that] shall be pleaded." 35 U.S.C. 282(1). That statutory requirement, however, "has never been deemed to alter the basic rule that a patentee bears the burden of proving infringement." 5B *Chisum on Patents* § 18.06[1][a], at 18-1181. Accordingly, an "accused infringer" may meet that "pleading burden with either a denial of a patentee's infringement allegation or by a positive asser-

2. Because this Court's decisions in *Railroad Co.* and *Imhaeuser* long predated the federal Declaratory Judgment Act, they did not contemplate or address the now-commonplace situation in which questions of patent coverage arise in a declaratory-judgment action commenced by the alleged infringer, rather than in an infringement suit initiated by the patent holder. Until the decision below, however, the relatively few lower-court decisions to address the question had recognized that an accused infringer does not assume the burden of proving noninfringement merely because it is a declaratory-judgment plaintiff. See 12 *Moore's Federal Practice* § 57.62[2][d], at 57-137 ("In patent, copyright, and trademark cases, courts have generally recognized that

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tion of noninfringement." *Ibid.* In certain circumstances, noninfringement might be treated as an affirmative defense. See 6 R. Carl Moy, *Moy's Walker on Patents* § 17:14, at 17-47 (4th ed. 2012) ("[A]llegations of noninfringement [under Section 282] can be denials of various assertions in the patent owner's complaint. They can also be various affirmative defenses, such as when the defendant alleges that the patent owner's recourse to the Doctrine of Equivalents has been barred by Prosecution History Estoppel.") (footnotes omitted); but see 5B *Chisum on Patents* § 18.06[1][a], at 18-1184.2 (noting that prosecution-history estoppel "presents a special problem," and that, although a defendant should be required to introduce evidence of the prosecution history and make "a prima facie showing," "[a]rguably, the ultimate burden of persuasion * * * should remain on the plaintiff"). When the relevant argument for noninfringement would take the form of an affirmative defense, the burden of proving that defense would likely be borne by the defendant. See *Schaffer*, 546 U.S. at 57 ("the burden of persuasion as to certain elements of a plaintiff's claim may be shifted to defendants, when such elements can fairly be characterized as affirmative defenses or exemptions"). But neither the Federal Circuit nor respondent has suggested that a noninfringement argument of the sort asserted by petitioner in this case would be treated as an affirmative defense outside the declaratory-judgment context.

any role reversal occasioned by declaratory relief should not shift the burden of proof from the manner in which it would be assigned in a coercive infringement suit."); 5B *Chisum on Patents* § 18.06[1][a], at 18-1182 to 18-1183 ("Courts apply the burden of proof to the patent owner" "in a declaratory judgment action initiated by the accused infringer."); Pet. Br. 36 & n.15 (citing cases). The courts had recognized that principle applied even in the absence of a counterclaim for infringement. See, *e.g.*, *Vivid Techs., Inc.* v. *American Sci. & Eng'g, Inc.*, 200 F.3d 795, 802 (Fed. Cir. 1999) (noting that "the parties bore the same evidentiary burdens whether or not the counterclaim [for infringement] was permitted"); Pet. Br. 36 n.16 (citing cases).

3. To prove infringement of a patent, the patent holder must make an affirmative showing that "every limitation set forth in a claim [is] found in an accused product or process exactly or by a substantial equivalent." *Becton Dickinson & Co.* v. *C.R. Bard, Inc.*, 922 F.2d 792, 796 (Fed. Cir. 1990). Accordingly, regardless of whether the patent holder asserts literal infringement or relies on the doctrine of equivalents, it must demonstrate how each limitation of the relevant claim maps onto the accused product. See *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) ("[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole."); *Southwall Techs., Inc.* v. *Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir.) (for literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly"), cert. denied, 516 U.S. 987 (1995).

A patent may include many claims. See Pet. Br. 44 (noting that "the two patents at issue here comprised more than 300 claims"). And, in some cases, there may be more than one way in which the limitations may be mapped (or may be claimed to map) onto the accused product. See, *e.g.*, *O2 Micro Int'l Ltd.* v. *Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1358 (Fed. Cir. 2006) (discussing three separate theories for which portion of the accused product constitutes a "feedback control loop"); *Becton, Dickinson & Co.* v. *Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1252 (Fed. Cir. 2010) (noting that patentee had impermissibly changed theories at trial regarding how the accused product employed a "spring means"). It makes sense to assign to the party alleging infringement the burden of demonstrating how the claim limitations map onto the accused product, because infringement may be found only when the product falls within the scope of the asserted claim or claims in every respect.

A contrary rule—under which the party denying infringement bears the burden of proof—would require that party to identify and negate every conceivable theory on which the product could infringe. In other words, "the alleged infringer would be forced to prove a negative, that no conceivable activity could infringe on any of the holder's rights." 12 *Moore's Federal Practice* § 57.62[2][d], at 57-137. "[P]racticality therefore favors placing the burden on the party asserting" infringement, rather than on the party attempting to disprove it. *NLRB* v. *Kentucky River Community Care, Inc.*, 532 U.S. 706, 711 (2001); *ibid.* (finding it reasonable to place the burden of proving supervisory status under the National Labor Relations Act on the party asserting that status, in part because "it is easier to prove an employee's authority to exercise 1 of the 12 listed supervisory functions than to disprove an employee's authority to exercise any of those functions"). That allocation of the burden of proof facilitates the orderly presentation of evidence and enables the parties and the court to focus on the theory of infringement asserted by the patent holder.

B. The Declaratory-Judgment Posture Does Not Require Shifting The Burden Of Proof Otherwise Associated With The Parties' Underlying Substantive Dispute

The court of appeals recognized the "general proposition that mere role reversal in a declaratory judgment action does not shift the burden" of proof on an issue from one party to the other. Pet. App. 11a. It observed, however, that "the burden of proving the allegations in [a] complaint" is "[g]enerally" borne by "the party seeking relief." *Id.* at 9a. On the basis of declaratory-judgment cases from the insurance context, the court concluded that it would be "fully consistent with other areas of the law" to require the burden in this case to "shift to the declaratory judgment plaintiff where the [defendant] is not seeking affirmative relief." *Id.* at 13a. That cursory analysis failed to account for several reasons why the declaratory-judgment posture does not support shifting the burden of proof in this case.

1. Declaratory-judgment plaintiffs do not invariably assume the burden of proof simply because they are plaintiffs

a. The court of appeals cited this Court's decision in *Schaffer* v. *Weast*, 546 U.S. 49, 56-57 (2005), for the proposition that "the party seeking relief"—*i.e.*, the plaintiff—generally "bears the burden of proving the allegations in his complaint." Pet. App. 9a. *Schaffer* was not a declaratory-judgment case, however, and the Court recognized that "[t]he ordinary default rule * * * admits of exceptions." 546 U.S. at 57. "[T]he burden of persuasion" sometimes will be placed on the defendant for "elements of a plaintiff's claim" that "can fairly be characterized as affirmative defenses or exemptions," and in some circumstances "this Court has even placed the burden of persuasion over an entire claim on the defendant." *Ibid.*

b. Like any other party invoking the jurisdiction of a federal court, a declaratory-judgment plaintiff must establish the constitutional and statutory prerequisites for such jurisdiction. See *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 95 (1993); see generally *DaimlerChrysler Corp.* v. *Cuno*, 547 U.S. 332, 342 (2006). This Court has not otherwise addressed the allocation of the burden of proof in the declaratory-judgment context. See, *e.g.*, *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 244 (1937). The Court has repeatedly observed, however, that "the operation of the Declaratory Judgment Act is procedural only." *Id.* at 240; see, *e.g.*, *Vaden* v. *Discover Bank*, 556 U.S. 49, 70 n.19 (2009); *Skelly Oil Co.* v. *Phillips Petroleum Co.*, 339 U.S. 667, 671 (1950); see also *MedImmune*, 549 U.S. at 138 (Thomas, J., dissenting) ("[T]he Act merely provides a different procedure for bringing an actual case or controversy before a federal court."). As petitioner explains (Br. 23-24), the purely procedural nature of the Declaratory Judgment Act strongly implies that it does not alter the burden of proof associated with an underlying claim, because this Court has "long held the burden of proof to be a 'substantive' aspect of a claim." *Raleigh* v. *Illinois Dep't of Revenue*, 530 U.S. 15, 20-21 (2000). Moreover, looking to the nature of the underlying dispute between the parties is consistent with the approach the Court has taken in determining whether a declaratory-judgment action implicates the right to a jury trial. See *Simler* v. *Conner*, 372 U.S. 221, 223 (1963) (per curiam).[6]

c. The court of appeals invoked cases from the insurance context to support its conclusion that a declaratory-judgment plaintiff should bear the burden of proof on a claim "where the [declaratory-judgment defendant] is not seeking affirmative relief." Pet. App. 13a. Two of the three insurance cases cited by the court of appeals, however, ultimately placed the burden of proof on the declaratory-judgment defendant (an insured), rather than on the insurance company that sought a declaratory judgment of non-coverage. The courts of appeals in those cases found that allocation of the burden appropriate because the substance of the underlying dispute turned on whether the insured was covered—a question on which, as a matter of applicable state insurance law, the insured bore the burden of proof.[7]

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[6] Petitioner also invokes (Br. 20-21) the application of the well-pleaded-complaint rule in *Franchise Tax Board* v. *Construction Laborers Vacation Trust*, 463 U.S. 1 (1983). This Court has noted in dictum, however, that it "is not clear" whether "a declaratory-judgment complaint raising a *nonfederal* defense to an anticipated *federal* claim * * * *would* confer [federal-question] jurisdiction" under 28 U.S.C. 1331. *Textron Lycoming Reciprocating Engine Div., Avco Corp.* v. *United Auto., Aerospace & Agric. Implement Workers of Am.*, 523 U.S. 653, 659 (1998).

[7] See *American Eagle Ins. Co.* v. *Thompson*, 85 F.3d 327, 331 (8th Cir. 1996) (finding "no reason to deviate from Arkansas [state-law] burden of proof principles [which place the burden of proving coverage on the person seeking insurance coverage] simply because this action was brought by the insurer under the federal Declaratory Judgment Act"); *Fireman's Fund Ins. Co.* v. *Videfreeze Corp.*, 540 F.2d 1171, 1174, 1176 (3d Cir. 1976) ("The burden of proof which usually accompanies the affirmative of the issue of coverage should not be shifted merely due to the [declaratory-judgment] form of the

In the third case, *Reliance Life Insurance Co.* v. *Burgess*, 112 F.2d 234 (8th Cir.), cert. denied, 311 U.S. 699 (1940), the court apparently placed the burden of proof on the insurance company, which was the declaratory-judgment plaintiff. That decision has been understood, however, as resting on the fact that the insurance company was asserting "an affirmative defense" stemming from a policy exclusion.[8] Because defendants often bear the burden of proving affirmative defenses, see *Schaffer*, 546 U.S. at 57, the insurer in *Burgess* therefore might have borne the burden of proof regarding the exclusion even if the suit had been commenced by the insured to obtain benefits alleged to be due. Thus, even if *Burgess* is assumed to have been correctly decided, it does not follow that petitioner's invocation of the declaratory-judgment mechanism should shift the burden of proof on the issue of infringement.

2. *A basic purpose of the Declaratory Judgment Act is disserved if the parties' nominal status as plaintiff or defendant is enough to alter the burden of proof in this context*

The Declaratory Judgment Act authorizes a court to provide "specific relief through a decree of a conclusive character" that adjudicates "the rights of the litigants" and thus resolves "a real and substantial controversy" between the parties." *Aetna*, 300 U.S. at 241. In many cases, including suits brought by alleged patent infringers to determine the scope or validity of a contested patent, the injury-in-fact that gives a declaratory-judgment plaintiff Article III standing is the threat of

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action"; applying "general law" in the absence of controlling Virgin Islands declaratory-judgment law), cert. denied, 429 U.S. 1053 (1977).

[8] *American Eagle Ins. Co.*, 85 F.3d at 331 (describing *Burgess*).

legal liability in an enforcement suit that could be, but has not been, brought against it by the declaratory-judgment defendant. See pp. 2-3, *supra*.

In such circumstances, the basic purpose and great utility of the Declaratory Judgment Act is to provide a mechanism for determining how *that enforcement suit* would be resolved without requiring, as a precondition to judicial resolution, that the declaratory-judgment plaintiff subject itself to retrospective liability. It would make little sense to require the declaratory-judgment plaintiff to bear the burden of proof on an issue as to which its adversary would have borne the burden in the correlative enforcement suit. That would detract from the understanding that the Declaratory Judgment Act was intended to provide an alternative procedural mechanism for "the same court, the same jurisdiction, the same procedure, the same parties and the same question." S. Rep. No. 1005, 73d Cong., 2d Sess. 3 (1934).[8]

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[8] In many suits where the plaintiff seeks declaratory relief pursuant to the Declaratory Judgment Act, his asserted injury has nothing to do with the possibility that suit might be filed against him. For example, a plaintiff might seek (perhaps in combination with other forms of relief) a declaration that the defendant's ongoing or impending conduct was violating or would violate federal or state environmental laws. To establish standing to sue, the plaintiff in such a case would need to show that he would personally be injured by the allegedly unlawful conduct. If a dispute arose concerning the applicable burden of proof on some subsidiary question, it would be arbitrary and perhaps incoherent to attempt to resolve that dispute by hypothesizing a coercive suit between the same parties in which the parties' alignment (as plaintiff and defendant) was reversed, and then asking who would bear the burden of proof on the issue in that context. That approach provides a useful guide, however, when the injury that the declaratory-judgment suit seeks to prevent is the imposition of legal liability in proceedings that might otherwise be instituted by the declaratory-judgment defendant.

In determining whether an accused device practices a particular patent, a court will undertake the same factual inquiry and apply the same rules of law, regardless of whether the question of patent coverage arises in a declaratory-judgment suit brought by the alleged infringer or in an infringement suit brought by the patent holder. The Declaratory Judgment Act would not retain its "procedural" character, see *Aetna*, 300 U.S. at 240, or fulfill its intended purpose of determining how an infringement suit brought by the patent holder would have been resolved, if the putative infringer's use of the declaratory-judgment mechanism triggered the application of a different body of substantive law. There is no sound reason to treat the rule that a patent holder bears the burden of proof on infringement, alone among the substantive legal rules that the court in an infringement suit would apply, as inapplicable to suits under the Declaratory Judgment Act.

That is particularly so because the practical justifications for requiring the patent holder to prove infringement apply equally in the declaratory-judgment context. As explained above (pp. 16-17, *supra*), a patent may contain many claims, and there may be more than one potential basis for alleging that a particular product infringes a particular claim. It would be just as unwieldy for a declaratory-judgment plaintiff to attempt to anticipate and disprove every potential theory of patent coverage as for an infringement defendant to do so.[10]

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[10] Moreover, to the extent that a different burden of proof would threaten the issue-preclusive effect of a proceeding in which the declaratory-judgment plaintiff loses its case (see Pet. Br. 32-33), that would detract from the ability of the Declaratory Judgment Act to provide for a "conclusive" resolution of the litigants' "rights." *Aetna*, 300 U.S. at 241; cf. *MedImmune*, 549 U.S. at 127-128 n.7 ("[A] litigant

C. The Existence Of A License Does Not Shift The Burden Of Proving Patent Infringement From A Patent Holder To Its Licensee

The court of appeals acknowledged both of the propositions discussed above: that a patentee generally bears the burden of proving infringement (Pet. App. 10a), and that, as a "general proposition," the "mere role reversal [of the parties] in a declaratory judgment action does not shift the burden" of proof (*id.* at 11a). The court found those usual principles inapplicable here, however, because it believed that, as a result of the parties' licensing arrangements, petitioner is "the only party seeking the aid of the court." *Id.* at 14a. The Federal Circuit's factual premises were incorrect, and its conclusion runs counter both to this Court's decision in *MedImmune* and to broader patent-law policies.

1. The parties' licensing arrangement does not resolve the dispute or alter the legal rules for determining whether petitioner's devices practice respondent's patents

The Federal Circuit stated that, when petitioner initiated this declaratory-judgment action, respondent was "foreclosed from counterclaiming for infringement by the continued existence of that license." Pet. App. 9a. The court further observed that "neither party here seeks money damages or an injunction based on patent infringement, which are the sorts of relief generally sought when a party seeks relief for patent infringement." *Id.* at 14a. The court viewed the licensing arrangement as a sound basis for re-allocating the burden

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may not use a declaratory-judgment action to obtain piecemeal adjudication of defenses that *would not finally and conclusively resolve* the underlying controversy.").

of proof on the issue of patent coverage, and it characterized petitioner as "seek[ing] a judicial decree absolving it of its responsibilities under its license." *Id.* at 9a.

The court of appeals was correct that, so long as petitioner complies with its obligations under the licensing and tolling agreements, it cannot be held liable for infringement, and petitioner cannot obtain damages or injunctive relief. The court erred, however, in treating that fact as a ground for requiring petitioner to prove that its devices do not practice respondent's patents.

a. This is not a case in which petitioner conceded (or promised not to contest) that a particular product practiced one of respondent's patents, but then attempted to litigate an issue that had been resolved by the parties' prior agreement. The 1991 license agreement does not require petitioner to acquiesce in respondent's assessment that particular devices practice respondent's patents. To the contrary, the agreement specifically contemplates that disputes regarding patent coverage may arise, and it establishes a structured process for resolving them. J.A. 13. Accordingly, the question that petitioner seeks to have answered (*i.e.*, whether its accused devices practice either of respondent's patents) is the very question that the license left open to be resolved by a court's declaratory judgment. As the Court said in *MedImmune*: "Petitioner is not repudiating or impugning the contract * * * . Rather, it is asserting that the contract, properly interpreted * * * does not require the payment of royalties *because the patents do not cover its products*." 549 U.S. at 135 (emphasis added).

b. Because the licensing and tolling agreements authorized petitioner to practice respondent's patents so long as petitioner complied with the agreement's terms (*e.g.*, by paying the contractually-specified royalties into a segregated fund), respondent could not succeed on any counterclaim for infringement damages even if it established that petitioner's devices were within the patent's scope. See 35 U.S.C. 271(a); J.A. 13 (licensing agreement provides that, so long as contractually-specified royalties are paid, respondent "shall not make claims for wilful infringement or punitive damages" and shall not "seek injunctive relief"); Br. in Opp. 16 (stating that respondent "did not assert infringement, and could not do so because [petitioner] was a licensee who had not breached its license"); pp. 11-12, *supra*. But while the agreement protected petitioner from potential liability for *infringement*, it did not pretermit judicial consideration of the question whether petitioner's devices *practice* respondent's patents.

Nor did the licensing arrangement suggest that the coverage question would be resolved under legal rules different from those that would apply in an infringement suit. To the contrary, the agreements between the parties, and respondent's own filings and communications, repeatedly use variants of the word "infringe" to refer to respondent's assertions that petitioner's devices practice the patents at issue here.[11] By stating that petitioner "shall have the right to challenge Lilly's assertion of infringement * * * through a Declaratory Judgment action," J.A. 13, the license agreement clearly authorized petitioner to contest respondent's assertions regarding patent *coverage*. And the terminology in the licensing and tolling agreements belies any inference that the parties viewed the concepts of patent infringement and patent coverage as meaningfully distinct.

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[11] See J.A. 13 (license agreement provides that, when "Lilly or the Mirowski family believes that [a Medtronic] device infringes one or more of the Mirowski patent(s), Lilly shall notify Medtronic of such infringement"); J.A. 23 (tolling agreement states that litigation is tolled for a period "after receipt by Medtronic of a notice of infringement from Guidant or Mirowski"); J.A. 28 (tolling agreement specifies that respondent will be "entitled to recover" royalties from the escrow account to the extent that petitioner's products are "held to infringe" respondent's patents); J.A. 48, 49 (respondent's answer to petitioner's declaratory-judgment complaint "admits that [respondent] has asserted that [several of petitioner's] products infringe at least one of [various claims in respondent's patents]").

c. The Federal Circuit also erred in concluding that petitioner—which "is paying money into escrow" and "wants to stop," Pet. App. 12a—"is the only party seeking the aid of the court," *id.* at 14a. In the court's view, petitioner needs to satisfy its burden of proof in order for "the court to disturb the status quo." *Id.* at 13a.

In fact, both parties are seeking to alter the status quo. The disputed royalties are currently in a segregated account established by petitioner. J.A. 22, 27. Once this case has been finally resolved, petitioner will be required under the terms of the tolling agreement to "cause distribution of the total amount in [that] account to [respondent] or to [petitioner] in a manner consistent with" the outcome of this case. J.A. 28. Respondent therefore has not yet received the royalties to which it believes it is entitled, and it (like petitioner) seeks a judicial decision that will cause money currently outside its control to be transferred to its possession.

That aspect of the parties' agreement further undermines the court of appeals' conclusion that petitioner should bear the burden of disproving patent coverage because respondent cannot counterclaim for infringement. The practical effect of the licensing and tolling agreements is to substitute one form of monetary relief (accumulated royalties in an amount agreed to by the parties) for another (infringement damages as determined by the court) if respondent ultimately prevails on the issues of patent coverage and validity. There is no sound reason to treat that remedial choice as a basis for altering the legal rules under which the merits of the suit will be adjudicated.

Thus, even assuming that the burden of proof generally should belong to the party that requests judicial relief, that proposition does no meaningful work in this case. The parties' licensing arrangement reflects their mutual agreement to have the scope of respondent's patents (and the extent of petitioner's royalty obligations) resolved in this declaratory-judgment action. The final decision in this case cannot possibly result in preservation of the status quo, but will necessarily produce affirmative relief for one side or the other.

2. **MedImmune** *and broader patent policy concerns counsel against the Federal Circuit's exception for licensees*

a. In *MedImmune*, this Court held that that the existence of a patent-licensing agreement (and a licensee's failure to breach the agreement) did not preclude the licensee from having an actual controversy with patent assignees that was sufficient, for purposes of Article III and the Declaratory Judgment Act, to support the licensee's request for a declaratory judgment that the underlying patent was invalid, unenforceable, or not infringed. 549 U.S. at 120, 137. The Court recognized that the licensee's continuing payment of royalties under the agreement eliminated any imminent risk that an infringement suit would be filed against it. *Id.* at 128. The Court concluded, however, that the licensee nevertheless had Article III standing to seek the declaratory judgment "because the threat-eliminating behavior was effectively coerced," *id.* at 129, by the prospect that the licensee's sales might be enjoined, and that the licensee might be subject to treble damages and attorney's fees, if it ceased making royalty payments, see *id.* at 122, 128.

The Court in *MedImmune* canvassed several of its declaratory-judgment precedents and concluded that "'the very purpose of the Declaratory Judgment Act [was] to ameliorate'" a recurring "dilemma." 549 U.S. at 129 (quoting *Abbott Labs.* v. *Gardner*, 387 U.S. 136, 152 (1967)). If the declaratory-judgment mechanism were not available, a person who believed particular conduct to be lawful, but who recognized that a court might ultimately reach a different conclusion, would be forced to choose "between abandoning his rights or risking" injurious consequences. *Ibid.*; see *id.* at 130-134. By continuing to make royalty payments under its license agreement, the licensee in *MedImmune* avoided the risk of a potential adverse judgment in a patent-infringement action, which could have resulted in an "order[] to pay treble damages and attorney's fees" and an injunction against selling a product that had "accounted for more than 80 percent" of its sales revenue for several years. *Id.* at 122.[12] The Court held that a justiciable controversy between the parties existed regarding the licensee's request for a declaratory judgment that the license agreement "does not require the payment of royalties because the patents do not cover its products and are invalid." *Id.* at 135.

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[12] Here, the license agreement authorized "terminat[ion of] the sublicense as to" respondent's patents if petitioner failed to pay royalties. J.A. 13. Like the licensee in *MedImmune*, petitioner would then have been forced to choose between withdrawing its allegedly-infringing products from the market and being exposed to treble damages and attorney's fees in a potential infringement action. See 35 U.S.C. 284, 285.

The Court in *MedImmune* had no occasion to discuss the proper allocation of burdens of proof in a declaratory-judgment action. The primary thrust of the Court's decision, however, was that the parties' agreement did not prevent the licensee from initiating suit because the declaratory-judgment mechanism would still serve its core purpose of ameliorating the dilemma that a potential infringer would otherwise face. Nothing in the decision suggests that, although a licensing agreement of this sort does not prevent a declaratory-judgment action from going forward *at all*, it alters the substantive rules that govern the suit's disposition.

In the decision below, the Federal Circuit expressed concern about transforming *MedImmune*'s "shield" into a "sword" that licensees could use to "hal[e] licensors into court." Pet. App. 14a. But the Declaratory Judgment Act's very purpose in this context is to give the alleged infringer access to a court, "even if the patentee has not filed an infringement action" against him. *Cardinal Chem.*, 508 U.S. at 95. And the prospect of being haled into court is precisely what the license agreement told respondent to expect when it gave notice that it believed petitioner's products infringed its patent.

b. By reducing the likelihood that the licensee will prevail, the Federal Circuit's burden-shifting rule would deter licensees' use of the declaratory-judgment mechanism, disserving the public interest in definitive judicial resolution of disputed issues of patent scope.

"The far-reaching social and economic consequences of a patent * * * give the public a paramount interest in seeing * * * that such monopolies are kept within their legitimate scope." *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). In overturning the prior doctrine of licensee estoppel, this Court explained that a rule precluding licensees from contesting the validity of the licensed patents would conflict with the strong federal policy favoring "full and free competition in the use of ideas which are in reality a part of the public domain." *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969). Although the dispute presently before this Court involves the scope rather than the validity of the relevant patents, it is equally important that "the holder of a patent should not be * * * allowed to exact royalties for the use of an idea * * * that is beyond the scope of the patent monopoly granted." *Blonder-Tongue Labs., Inc.* v. *University of Ill. Found.*, 402 U.S. 313, 349-350 (1971); see *Morton Salt Co.* v. *G.S. Suppiger Co.*, 314 U.S. 488, 492 (1942) ("[T]he public policy which includes inventions within the granted monopoly excludes from it all that is not embraced in the invention."); cf. *Treemond Co.* v. *Schering Corp.*, 122 F.2d 702, 705 (3d Cir. 1941) ("Manifestly, the threat is as unjust if the [declaratory-judgment] plaintiff is not infringing a valid patent as it is if he is infringing an invalid one.").

To be sure, the court below did not treat the licensing agreement in this case as a ground for outright dismissal of petitioner's declaratory-judgment suit. By shifting to the licensee a burden of proof that the patent holder would otherwise have borne, however, the court impeded licensees' use of the Declaratory Judgment Act to obtain definitive judicial resolution of issues of patent scope. Accordingly, the same kinds of policy concerns that encouraged this Court to overturn the doctrine of licensee estoppel (see *Lear*, *supra*) and to permit patent licensees to seek declaratory judgments without violating their licenses (see *MedImmune*, *supra*) warrant reversal of the Federal Circuit's judgment here.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

DONALD B. VERRILLI, JR.
Solicitor General
STUART F. DELERY
Acting Assistant Attorney General
MALCOLM L. STEWART
Deputy Solicitor General
CURTIS E. GANNON
Assistant to the Solicitor General
SCOTT R. MCINTOSH
DANIEL TENNY
Attorneys

BERNARD J. KNIGHT, JR.
General Counsel
NATHAN K. KELLEY
Deputy Solicitor
MICHAEL S. FORMAN
WILLIAM LAMARCA
Associate Solicitors
United States Patent and Trademark Office

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MEDTRONIC, INC.,

Petitioner,

v.

BOSTON SCIENTIFIC CORP., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF RESPONDENTS

RICHARD F. PHILLIPS,
PRESIDENT
KEVIN H. RHODES, CHAIR
AMICUS BRIEF COMMITTEE
INTELLECTUAL PROPERTY
OWNERS ASSOCIATION
1501 M Street, N.W.
Suite 1150
Washington, D.C. 20005
(202) 507-4500

GARY M. HOFFMAN
Counsel of Record
7428 Old Maple Square
McLean, VA 22102
(703) 819-7517
gmhoffmanfl@aol.com

DAWN L. RUDENKO
DICKSTEIN SHAPIRO LLP
1633 Broadway
New York, New York 10016

Attorneys for Amicus Curiae

240660

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

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INTEREST OF *AMICUS CURIAE*

Amicus curiae Intellectual Property Owners Association (IPO) is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in U.S. intellectual property rights.[1] IPO's membership includes more than 200 companies and a total of over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the USPTO and has filed amicus curiae briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the appendix.[2]

INTRODUCTION

In the modern economy, licensing of intellectual property rights is a widespread and essential activity.

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *Amicus Curiae* or its counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

[2] IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting. Medtronic, Inc. is a member of IPO's Board of Directors; however, it did not participate in the discussions regarding or vote on the decision to file this brief, and did not participate in its preparation.

IPO members are owners of intellectual property rights, which are commonly the subject of license agreements that are entered into to settle litigation, to gain access to technology, to generate a revenue stream for inventors, and for myriad other reasons. The issue presented in this case centers on whether a rigid rule that the licensor always bears the burden of proof on whether the licensee's products are outside the scope of the license results in an unwarranted obligation on the licensor, unless the parties have agreed to allocate the burden of proof in that manner.

The issue here does not challenge this Court's decision in *MedImmune, Inc. v. Genentech, Inc.* providing the licensee with the right to challenge the licensed patent without breaching the license agreement. 549 U.S. 118 (2007). Rather, the only issue here is the narrow question of who bears the burden of proof on the issue of whether the licensee's products are outside the scope of the licensed patent, in the event that the licensor does not, or cannot, allege infringement and the license agreement itself does not allocate the burden of proof.[3]

This is not purely an issue of patent law. At its heart, it is an issue of contract law, and the impact of requiring a licensor to prove infringement – when the licensor has not and cannot allege infringement and can do nothing more than seek to be discharged from the suit and maintain the status quo due to the continued existence of a negotiated, arms-length license (including where the license was granted to avoid litigation or in the settlement of prior litigation). There is no support, in law or logic, to apply the general patent rule requiring a patent owner to prove infringement in a post-*MedImmune* license challenge. Indeed, as this Court has previously recognized, established equitable principles apply with equal force to patent disputes.

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[3] This is not a situation where the courts can—and should—enforce a contractual allocation of the burden of proof for challenges to licensed product royalty obligations where the licensor and licensee include such a provision in the license agreement.

The Federal Circuit, in *Medtronic*, properly applied the equitable principles of contract law in this case.[4] Recognizing the general rule that the patent owner generally bears the burden of proof on the issue of infringement, even as a defendant in declaratory judgment action, the Federal Circuit distinguished this general principle to the narrow facts of a particular type of post-*MedImmune* license challenge. The Federal Circuit's holding applies only where the patent owner has not – and cannot – allege infringement and is seeking no relief other than to be discharged from the suit and maintain the status quo. The Federal Circuit's holding is wholly consistent with the well-established principle that the challenger generally bears the burden of proving the allegations in its complaint. It also reinforces the strong public interest in upholding the creation of contracts and in the settlement of litigation.

To permit a licensee to maintain the status quo, force the licensor to prove infringement—even where the licensor cannot plead it, let alone seek infringement remedies—and suffer no negative impact even if the licensee loses, would cause a significant imbalance between a patentee-licensor and a licensee. Indeed, such a holding may effectively render patent licenses, whether entered in advance to resolve potential disputes or to settle litigation, worth nothing more than the paper upon which they are written—at least for the patentee-licensor.

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[4] It is recognized that the Solicitor General has submitted an *Amicus* Brief recommending reversal of the Federal Circuit. For the reasons explained herein, IPO respectfully disagrees with the Solicitor General's reasoning since it largely ignores the primacy of contract law in defining the relationship between the licensor and the licensee.

SUMMARY OF ARGUMENT

This Court has long recognized the sometimes diametric interests of encouraging and protecting the formation of contracts and litigation settlements against the need to "weed out" invalid and unenforceable patents. *Lear, Inc. v. Adkins*, 395 U.S. 653, 668 (1969). Balancing these interests oft-times requires carving out exceptions to general rules, and applying the most relevant (and logical) law to specific facts of particular legal situations. This is what the U.S. Court of Appeals for the Federal Circuit properly did here in deciding the narrow issue of placing the burden of proof on the licensee where the licensee has filed a declaratory judgment action asserting that its products are not covered by the licensed patent and the licensor cannot counterclaim for infringement. This exception to the general rule does not conflict with any policy favoring the "weeding out" of an invalid patent from being a block to others in the field; here there is no challenge to patent validity, but merely a private dispute between two parties as to whether the licensed patent covers certain of the licensee's products.

The Federal Circuit relied upon long-established precedent in holding that the party seeking relief bears the burden of proving the allegations in the complaint. *Medtronic Inc. v. Boston Scientific Corp.*, 695 F.3d 1266, 1272 (Fed. Cir. 2012 (quoting *Schaffer ex rel. Schaffer v. Weast*, 546 U.S. 49, 56-57 (2005) ("Perhaps the broadest and most accepted idea is that the person who seeks court action should justify the request ....")). Acknowledging the general rule that a patentee bears the burden of proving infringement when asserting infringement, the Federal Circuit appropriately identified the narrow circumstances when the burden should properly be on an infringement challenger—where a licensee in good standing seeks a declaratory judgment of non-infringement under a post-*MedImmune* license, foreclosing an infringement counterclaim, as is proper in any case where the plaintiff alone seeks relief. *Medtronic*, 695 F.3d at 1274. To hold otherwise, would have an unintended impact on patent licenses and settlements, placing them outside established contract law.

The Federal Circuit's holding is in harmony with this Court's *MedImmune* and *Lear* decisions. It also strikes the only rational balance in allowing a licensee to use the license as a shield under *MedImmune*, while preventing it from using it as a Damoclean sword against the patentee in challenging a license at its sole discretion and benefit. The public's interest in ensuring such a balance is particularly crucial in the area of patent licensing. IPO therefore urges this Court to affirm the judgment of the Federal Circuit.

ARGUMENT

I. Medtronic is Limited to Cases Where the Patentee Cannot Assert Infringement Against A Licensee and Follows the Well-Settled Rule that the Party Seeking Relief Bears the Burden of Persuasion

The Federal Circuit's holding in *Medtronic* applies to narrowly defined circumstances:

> [w]hen an infringement counterclaim by a patentee is foreclosed by the continued existence of a license, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion.

Medtronic, 695 F.3d at 1274 (emphasis added). The relief Medtronic seeks relates directly to its obligations under the license. Medtronic already has a license; it cannot be sued for infringement. The ongoing license prohibits the assertion of such a claim by the patentee. *Id.* at 1273. The contract-at-issue requires MVF[5] to identify products that it believes fall within the contract. After they are identified, Medtronic is required to either pay royalties or sue for declaratory judgment. Medtronic filed for declaratory judgment. MFV can seek nothing more than to be discharged from the suit and maintain the status quo. Medtronic is the only party seeking relief.

The Federal Circuit followed the well-established equitable principle that the challenger generally bears the burden of proving the allegations in its complaint. *Medtronic*, 695 F.3d at 1272 (citing *Schaffer ex rel. Schaffer v. Weast*, 546 U.S. 49, 56-57 (2005)). There is no rationale to shift the burden to the patentee merely because the licensee asserts non-infringement to avoid paying a royalty. To do so would create an unintended loophole in contract and patent law that would effectively render patent licenses (at least from the perspective of a patentee-licensor) of little worth. As this Court recognized in *Ebay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391-92 (2006), established equitable principles apply with equal force to disputes arising under the Patent Act: "[a] major departure from the long tradition of equity practice should not be lightly implied."

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[5] Respondent Mirowski Family Ventures, LLC.

II. The Federal Circuit's Holding in *Medtronic* Does Not Conflict with *MedImmune*

The *Medtronic* decision is not in conflict with *MedImmune*. This Court in *MedImmune* resolved a narrow jurisdictional issue, specifically whether a patent licensee is to terminate or breach a license agreement to meet the case or controversy criterion under Article III before seeking a declaratory judgment that the licensed patent is invalid, unenforceable or not infringed. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 120-21 (2007). *MedImmune* narrowly held that there was a justiciable controversy even if the licensee continued to pay royalties to the patentee to avoid breaching the license. *Id.* at 137.

The relevant issue before the Federal Circuit in *Medtronic* was whether the patent licensee or the licensor bears the burden of proving non-infringement as it relates to the scope of the contract in a post-*MedImmune* declaratory judgment action. *Medtronic*, 695 F.3d at 1272. Following well principled law, the Federal Circuit held that when an infringement counterclaim is foreclosed by the continued existence of a license, the licensee seeking declaratory judgment of non-infringement and of no consequent liability under the license bears the burden of persuasion. *Id.* at 1272-74.

MedImmune neither addressed the *Medtronic* issue, nor held that a patentee has the burden of proof where it does not (and indeed legally cannot) counterclaim for infringement and the only party requesting relief is the licensee.[6]

III. The Federal Circuit's Decision in *Medtronic* Does Not Conflict with the Public Policy Concerns in *Lear*

This Court, in *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969), abolished the doctrine of licensee estoppel, holding that in the interest of public policy to cull out invalid and unenforceable patents, licensees cannot generally be barred by the terms of a license from repudiating that license and challenging a patent.

Medtronic concerns a declaratory judgment of non-infringement. Unlike the public's interest in eradicating invalid and unenforceable patents recognized in *Lear*, the only interests at stake in determining infringement under a license are those of the parties. This is not in conflict with the general policy favoring contracts and settlement of patent disputes. There is no broader supervening public interest involved in determining the scope of the patent license between the licensor and licensee.

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[6] As more fully addressed in Section IV, IPO does not believe that it was the intent of this Court to apply *MedImmune* to non-infringement challenges of post-*MedImmune* licenses, where the licensor is not legally permitted to counterclaim for infringement.

IV. The Public's Interest Will Be Best Served by Requiring the Patent Licensee to Prove Non-Infringement under a *MedImmune* Declaratory Judgment Action

The Federal Circuit opinion recognizes the imbalance and burden upon patent owners that would be created if a licensee could—at its sole discretion—force the patentee into full-blown patent-infringement litigation, requiring the licensor to prove infringement, but not be able to assert it; and even if successful, its efforts are simply to maintain the status quo of an already, fully negotiated, existing contract. Whereas, the successful outcome for the licensee is termination of its payment obligation under the contract. And the worst-case scenario for the licensee is that it continues paying what it previously contracted to pay. This cannot be the intended effect of *MedImmune*.

In a post-*MedImmune* patent license challenge, the patent-owner licensor is prevented from counterclaiming infringement against the licensee. The unintended, negative implications of requiring a patent owner to prove infringement to hold a licensee to its bargain, while not being able to assert infringement, are legion.

While patent licenses, as a business decision or to avoid litigation though settlement, are to be encouraged, placing the burden (and all of the risk) on the patent owner who has no upside other than maintaining the license already negotiated would serve to create disincentives to patent licenses and settlements. If the patent owner needs to fully litigate patent infringement after it has entered into a contract—to which it is solely bound and for the purpose of avoiding such a scenario—the primary perceived benefit to doing so is obliterated. A licensor's most secure path would be to initiate or proceed with litigation and seek a higher, enforceable and more certain recovery. Meanwhile the accused infringer would be able to take a license, lock in the maximum royalty rate and still be able to fully litigate the issues with the licensor still bearing the burden of proof on infringement.

This Court has repeatedly recognized that public policy encourages and favors both the formation of contracts and the settlement of legal disputes. *Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367, 406 (1992) (dissenting); *United States v. Singer Mfg. Co.*, 374 U.S. 174, 199 (1963) (concurring). Each is particularly valuable with respect to patents and the avoidance of patent disputes. *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("there is strong public interest in settlement of patent litigation and that upholding the terms of a settlement encourages patent owners to agree to settlements"); *Joy Mfg. Co. v. Nat'l Mine Serv. Co.*, 810 F.2d 1127, 1131 (Fed. Cir. 1987) (Newman, J. concurring).

As a general rule, contracts by competent persons, equitably made, are valid and enforceable. Indeed, this Court has stated:

> [I]f there is one thing which more than another public policy requires it is that men of full age and competent understanding shall have

> the utmost liberty of contracting, and that their contracts, when entered into freely and voluntarily, shall be held sacred, and shall be enforced by courts of justice. Therefore, you have this paramount public policy to consider – that you are not lightly to interfere with this freedom of contract.

Baltimore & Ohio Sw. Ry. Co. v. Voigt, 176 U.S. 498, 505-06 (1900); *Twin City Pipe Line Co. v. Harding Glass Co.*, 283 U.S. 353, 356 (1931) ("The general rule is that competent persons shall have the utmost liberty of contracting and that their agreements voluntarily and fairly made shall be held valid and enforced in the courts."). Parties to a contract are bound by the terms to which they have agreed, even if the terms appear to be improvident or one-sided, as long as the contract is not a result of fraud, duress or undue influence. Williston On Contracts § 3.2 (4th ed. 2013). The binding force of a contract derives from the fact that it evinces a meeting of minds. *Id.* A contract, once formed, does not contemplate a right of a party to reject it. *Id.*, § 3.5.

A current reality is that many sophisticated parties voluntarily seek to resolve in advance any potential patent disputes through contract. Indeed, patent licenses often appear as significant components of the consideration in broader business arrangements between sophisticated parties. These arrangements (e.g., cross-licenses, package licenses, freedom-to-operate, joint-development agreements, standards-related licensing policies) often provide the parties freedom of action to design and market products in the face of rapidly evolving technologies and a cloudy picture (at best) of the landscape of future patent protection. A crucial component of these agreements is to permit the parties to avoid the uncertainty and costs associated with full-blown patent litigation. These agreements should be handled and resolved under the procedural and substantive rules of contract law. In particular, the burden of proof should fall upon the party who challenges the express terms of the contract and who is otherwise seeking the requested relief. *Schaffer*, 546 U.S. at 56 (quoting C. Mueller & L. Kirkpatrick, Evidence § 3.1 (3d ed. 2003)).

A contrary outcome would turn contract law on its head. The licensor cannot charge a licensee with infringement; it cannot cancel the license; it is obligated to comply with the terms of the contract. *Medtronic*, 695 F.3d at 1273. A patentee-licensor, as held by *MedImmune*, is bound by the license. By entering a patent license, the patentee forfeits its right to many types of potential statutory damages and remedies, i.e., enhanced damages, trebled damages, injunction and higher royalty rates. A licensor enters into these types of agreements believing that they will be enforceable as to both parties for the subject matter to which they were executed. To remove the certainty and protections afforded by patent licenses will significantly stifle patent owners' willingness to enter into patent agreements and resolve patent disputes.

A contrary outcome will equally impact the desirability of patent settlements. Patent litigations are often settled through licensing for the purpose of avoiding the uncertainties and costs associated with protracted litigation. If a litigation licensee could then challenge the settlement license for non-infringement–avoiding the risks associated with infringement, while imposing the burden of persuasion on the patentee-licensor, with the only reward available to the licensor being the already settled rate—the result would significantly dampen patentees' readiness to settle patent disputes through license, thus harming the corresponding public interest.

The reasoning in *Digital Equipment Corp. v. Desktop Direct, Inc.*, 511 U.S. 863 (1994) shows this Court's sensitivity to deterring parties' readiness to settle disputes. In *Digital Equipment Corp.*, this Court rejected the argument that precluding interlocutory appeals from orders vacating settlements would hinder settlements and frustrate the strong federal policy favoring voluntary resolution of disputes. The Court stated that it:

> [d]efies common sense to maintain that parties' readiness to settle will be significantly dampened (or the corresponding public interest impaired) by a rule that a district court's decision to let allegedly barred litigation go forward may be challenged as a matter of right only on appeal from a judgment for the plaintiff's favor.

Digital, 511 U.S. at 881. Here, for a patentee to be forced to prove infringement for the sole benefit of continuing the licensed-settlement rate is not an incentive to enter into patent agreements or to settle patent disputes through license. Such a decision would pose a great obstacle to providing royalties at discounted rates and rates based on the assumption that there will be no litigation costs or risks related to infringement. Even if successful, the patentee ultimately would be the loser. A patent owner would be foolish to agree to a patent-settlement license under this situation.

The practical effect would be that these types of licenses would only be operative against the licensor. The licensee would be free to challenge any patent claims resolved under an already negotiated, arms-length contract. This would truly be the proverbial "have its cake and eat it too" situation. A licensee would be permitted to avoid all of the risks associated with being held an infringer through litigation by entering into a license. Then it could simply challenge the scope of the royalty obligation under the license claiming non-infringement. If the licensee is successful—perfect—no royalties are due; if it loses (found to infringe), it simply must live by the terms of the previously negotiated license. The result would be a loophole to allow licensees and potential infringers to avoid both contract and patent infringement laws. Because this Court was not considering this issue in *MedImmune*, IPO suggests that this was not the intended result of the *MedImmune* decision.

CONCLUSION

IPO urges the Court to affirm the Federal Circuit's decision below. Otherwise, any potential infringer may enter into a patent contract or settlement agreement, then challenge that contract under *MedImmune* claiming that they do not infringe, thereby, removing the risks associated with a ruling of infringement. This would occur all while the patentee exists as nothing more than a party to a contract—bound to its terms, even if it wins—and receiving nothing more than maintaining the contract that it had previously negotiated at arms-length to avoid this exact scenario.

The licensee has everything to gain in entering such a contract. The licensor has everything to lose (i.e., the license, higher rates, injunction, treble damages). A ruling supporting this result will significantly weaken contract and patent law. And it will have a significantly negative effect on patent licenses and settlements. For these reasons, IPO respectfully requests that this Court affirm the Federal Circuit's ruling.

Dated: September 23, 2013

Respectfully Submitted,

RICHARD F. PHILLIPS,
PRESIDENT
KEVIN H. RHODES, CHAIR
AMICUS BRIEF COMMITTEE
INTELLECTUAL PROPERTY
OWNERS ASSOCIATION
1501 M Street, N.W.
Suite 1150
Washington, D.C. 20005
(202) 507-4500

GARY M. HOFFMAN
Counsel of Record
7428 Old Maple Square
McLean, VA 22102
(703) 819-7517
gmhoffmanfl@aol.com

DAWN L. RUDENKO
DICKSTEIN SHAPIRO LLP
1633 Broadway
New York, New York 10016

Attorneys for Amicus Curiae

APPENDIX[1] — MEMBERS OF THE BOARD OF DIRECTORS INTELLECTUAL PROPERTY OWNERS ASSOCIATION

Tina M. Chappell
Intel Corp.

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Xerox Corp.

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Bristol-Myers
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Horacio Gutierrez
Microsoft Corp.

Jack E. Haken
Koninklijke Philips N.V.

Jennifer M. Hall
Mars Inc.

Alan W. Hammond
Life Technologies Corp.

---

[1] IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

Appendix

Dennis R. Hoerner, Jr.
Monsanto Co.

Carl B. Horton
General Electric Co.

Michael Jaro
Medtronic, Inc.

Philip S. Johnson
Johnson & Johnson

Lisa K. Jorgenson
STMicroelectronics, Inc.

Charles M. Kinzig
GlaxoSmithKline

David J. Koris
Shell International B.V.

Allen Lo
Google Inc.

Timothy F. Loomis
Qualcomm, Inc.

Steven W. Miller
Procter & Gamble Co.

Douglas K. Norman
Eli Lilly and Co.

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Covidien

Sean O'Brien
United Technologies Corp.

Richard F. Phillips
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Dana Rao
Adobe Systems Inc.

Kevin H. Rhodes
3M Innovative Properties Co.

Mark L. Rodgers
Air Products & Chemicals, Inc.

Curtis Rose
Hewlett-Packard Co.

Matthew Sarboraria
Oracle USA Inc.

Manny Schecter
IBM Corp.

Steven J. Shapiro
Pitney Bowes Inc.

Dennis C. Skarvan
    Caterpillar Inc.

Russ Slifer
    Micron Technology, Inc.

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    Motorola Solutions, Inc.

Daniel J. Staudt
    Siemens Corp.

Brian K. Stierwalt
    ConocoPhillips

Thierry Sueur
    Air Liquide

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    BP America, Inc.

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    Pfizer, Inc.

Michael Walker
    DuPont

BJ Watrous
    Apple Inc.

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    Amgen, Inc.

Paul D. Yasger
    Abbott Laboratories

Michael Young
    Roche, Inc.

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MEDTRONIC, INC.,

Petitioner,

v.

BOSTON SCIENTIFIC CORPORATION,
GUIDANT CORPORATION, AND
MIROWSKI FAMILY VENTURES, LLC,

Respondents.

**ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

BRIEF OF KONINKLIJKE PHILIPS, N.V. AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

JACK E. HAKEN
Counsel of Record
MICHAEL FUERCH
YAN GLICKBERG
LAURIE GATHMAN
DAVID SCHREIBER
PHILIPS INTELLECTUAL
PROPERTY AND STANDARDS
345 Scarborough Road
Briarcliff Manor, New York 10510
(914) 333-9650
jack.e.haken@philips.com

240118

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QUESTION ADDRESSED BY *AMICUS CURIAE*

When a licensee seeks a declaratory judgment that its products do not practice a patent, which party bears the burden of proof regarding patent infringement?

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Mike Masnick, *There Are 250,000 Active Patents That Impact Smartphones; Representing One In Six Active Patents Today*, Innovation (Oct. 18, 2012, 8:28 AM), http://www.techdirt.com/blog/innovation/articles/20121017/10480520734/there-are-250000-active-patents-that-impact-smartphones-representing-one-six-active-patents-today.shtml 2

Robert E. Scott & George G. Triantis, *Anticipating Litigation in Contract Design*, 115 YALE L.J. 814 (2006) 6

INTEREST OF THE *AMICUS CURIAE*

Amicus Curiae Koninklijke Philips N.V. is the parent corporation of a worldwide family of companies ("Philips").[1] Philips has been inventing and manufacturing electronic and electrical products for over 120 years and is one of the largest users of the patent system in the United States and other industrialized countries.

Last year, Philips filed U.S. patent applications for over 1300 inventions. Scientists and engineers at our laboratories have made pioneering advances in the fields of high efficiency lighting, medical diagnosis and imaging, high definition television, optical CD and DVD recording, and digital rights management. Philips receives hundreds of millions dollars as annual income from patent licensing activities. Philips is both a licensor and a licensee of patent rights, and we have a strong interest in ensuring the efficient operation of license agreements, both inside and outside of a litigation context. As such, Philips' interest is in having a clear and appropriate rule regarding the burden of persuasion in declaratory judgment actions of non-infringement. An equally important interest of Philips is the strong public policy consideration of freedom of contract, and we would hope that such a rule will be set forth in a manner that does not frustrate the ability of sophisticated parties to freely contract to place the burden of persuasion where they see fit.

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[1] *Amicus Curiae* submits this brief with written consent of the parties. Such consents are being submitted herewith. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation of submission of this brief. No person other than *amicus curiae* made a monetary contribution intended to fund its preparation or submission.

INTRODUCTION

This case presents the question of whether the burden of persuasion should lie with the patentee or the party seeking relief in a declaratory judgment action of non-infringement. The landscape of the patent licensing business arena has substantially changed in recent years. In the past, the majority of reported patent license disputes involved agreements that were made to settle infringement litigation or which simply permitted manufacture of identified products under a single patent, or perhaps a few related patents. But today, popular consumer and commercial products typically must comply with government and private standards and are arguably covered by tens or even hundreds of patents.[2] Sophisticated companies bargain for design freedom by entering into broad, forward-looking licenses and non-assertion agreements. Oftentimes those bargains are directed to bundles of patents and other intellectual property rights and they intentionally capture potentially weak patents along with other strong and potentially essential rights. The licensor and licensee both recognize the relative strengths and risk factors and the price paid for the license is essentially a cost of insurance against those risks.[3]

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[2] There are reportedly 250,000 active United States patents that impact "smart" mobile telephones. Mike Masnick, *There Are 250,000 Active Patents That Impact Smartphones; Representing One In Six Active Patents Today*, Innovation (Oct. 18, 2012, 8:28 AM), http://www.techdirt.com/blog/innovation/articles/20121017/10480520734/there-are-250000-active-patents-that-impact-smartphones-representing-one-six-active-patents-today.shtml.

It is also important to appreciate that patent license and non-assertion commitments frequently arise as components of sophisticated technology development and transfer partnerships.[4] There is an undesirable likelihood for upsetting the balance of these arrangements if the patent aspects are treated in isolation from the other business and technical arrangements.

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[3] "Thus, package licensing [of essential patents with non-essential patents] provides the parties a way of ensuring that a single licensing fee will cover all the patents needed to practice a particular technology and protecting against the unpleasant surprise for a licensee who learns, after making a substantial investment, that he needed a license to more patents than he originally obtained. . . . [G]rouping licenses in a package allows the parties to price the package based on their estimate of what it is worth to practice a particular technology, which is typically much easier to calculate than determining the marginal benefit provided by a license to each individual patent." *U.S. Philips Corp. v. Int'l Trade Comm'n*, 424 F.3d 1179, 1193 (Fed. Cir. 2005).

[4] The patent statutes have been repeatedly amended in recent years to account for the effects of joint research agreements and the ownership of patents for inventions made in the course of those agreements. The provisions of 35 U.S.C. § 103, which apply to patent applications and patents filed prior to March 16, 2013, effectively allowed participants in joint development agreements to obtain overlapping patents on otherwise obvious variants of the same invention. Pursuant to the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), those provisions were repealed with respect to newer patent applications and replaced with provisions that are now incorporated in Sections 35 U.S.C. 100 and 102(c).

Prior to this Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), a licensee did not have declaratory judgment jurisdiction while it continued to make royalty payments under a license agreement. Today, a licensee may freely challenge the validity of a licensed patent without breaching the license agreement and opening itself up to the possibility of an infringement suit by the patentee. *Id.* at 137. Similarly, where a licensor and licensee dispute patent scope pertaining to one of the licensee's products, the licensee may be able to obtain relief from certain obligations under the license agreement by seeking a declaratory judgment of non-infringement. Philips supports the Respondents' assertion that the burden of persuasion in this case should rest with the licensee; we stand with the positions set forth in the Intellectual Property Owners Association's *amicus* brief.[5]

However, even if the Court holds that the patentee should bear the burden of persuasion in this case, we strongly believe that the Court should also expressly acknowledge that sophisticated parties' retain freedom, via contract, to shift the burden of persuasion relating to patent infringement to the licensee. The arguments submitted herein are thus focused on this aspect.

SUMMARY OF THE ARGUMENT

Philips supports the Respondents' assertion that the burden of persuasion in this case should rest with the licensee, and we stand with the positions set forth in the Intellectual Property Owners Association's *amicus* brief. Absent controlling authority, reasonable minds may differ as to how the burden of proof (or persuasion) ought to be assigned. We respectfully submit that no one view will fit every situation and therefore the parties are in the best position to understand the particulars of their situation and to negotiate and bargain in an effort to reach a fair allocation of burden(s) through contract, if they so choose.

---

[5] Philips is a member of the Intellectual Property Owners Association (IPO) and participated on the IPO Board of Directors and the IPO *Amicus* Brief Committee that debated and approved the IPO *amicus* brief.

ARGUMENT

I. SHIFTING THE BURDEN OF PERSUASION REGARDING INFRINGEMENT SHOULD BE ALLOWED BY CONTRACT

Courts have traditionally allowed parties to contractually agree to modify litigation rights and rules. For instance, this Court has enforced a contractual agreement in which a party waived objection to personal jurisdiction despite the absence of minimum contacts with the forum. *Nat'l Equip. Rental, Ltd. v. Szukhent*, 375 U.S. 311, 315-16 (1964). Individuals may waive their due process rights by appointing an agent for service of process in that forum. *Id.* Similarly, forum selection clauses are often included in contracts and enforced by the courts. Other litigation rights have also been contractually determined, including waiver of notice and hearing, right to trial by jury, arbitration, and certain rules of evidence and rules of civil procedure.[6] Absent controlling authority, reasonable minds may differ as to how the burden of proof (or persuasion) ought to be assigned.[7] We respectfully submit that no one view will fit every situation and therefore the parties are in the best position to understand the particulars of their situation and to negotiate and bargain in an effort to reach a fair allocation of burden(s) through contract, if they so choose.[8]

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[6] *See generally* Henry S. Noyes, *If You (Re)Build It, They Will Come: Contracts to Remake the Rules of Litigation in Arbitration's Image*, 30 HARV. J.L. & PUB. POL'Y 579 (2007).

Other *amici* appear to be in agreement that sophisticated parties should be free to shift the burden of persuasion as they deem appropriate by contract. Tessera Technologies, Inc. asserts that the lower courts must be given a chance to consider "whether the parties contracted out of the default choice-of-law rule on the burden of persuasion," implicitly acknowledging that such contracting around would be appropriate. *See* Brief for Tessera Technologies, Inc. as *Amicus Curiae* 37. Further, the United States notes that "[n]othing in the . . . agreements suggests that the parties intended the courts to do anything other than apply the same legal rules that would govern a similar declaratory judgment action between [different] parties," again signaling that a contractual agreement that explicitly shifted the burden of persuasion should compel a different result. *See* Brief for United States as *Amicus Curiae* 10.[9]

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[7] Robert E. Scott & George G. Triantis, *Anticipating Litigation in Contract Design*, 115 YALE L.J. 814 (2006). For example, a licensee may agree to accept a burden-shifting provision prior to any infringement dispute in exchange for a lower royalty rate, or some other concession.

[8] *See* Noyes, *supra* note 6, at 601. We recognize that there might be instances where parties should not be allowed to reallocate these burdens, if, for instance, parties to an agreement have a different level of understanding or sophistication with regard to the transaction or bargaining posture, or if such an allocation would contradict a statute.

With respect to the facts of the subject case, the Declaratory Judgment Act of 1934, Ch. 512, 48 Stat. 955, provides a remedy for patent licensees to seek an early adjudication of a patent infringement threat. The statute provides that "any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such." 28 U.S.C. § 2201(a). It is respectfully submitted that because neither the Declaratory Judgment Act nor the provisions of Title 35 of the United States Code state or imply how the burden of persuasion should be allocated, the parties should be permitted to allocate the burden as they see fit.

---

[9] Other courts have implied that the burden of proof may be shifted by contract. *See, e.g., In re Marine Sulphur Queen*, 460 F.2d 89, 103-04 (2d Cir., 1972) ("[I]n light of the fact that the ordinary burden of proof between a private shipper and carrier was not altered either by statute or contract, the [default] rule . . . prevails.").

CONCLUSION

For the foregoing reasons, the Federal Circuit's judgment should be affirmed, and sophisticated parties should be free to shift, by contract, the burden of persuasion regarding infringement.

Respectfully Submitted,

JACK E. HAKEN
Counsel of Record
MICHAEL FUERCH
YAN GLICKBERG
LAURIE GATHMAN
DAVID SCHREIBER
PHILIPS INTELLECTUAL
PROPERTY AND STANDARDS
345 Scarborough Road
Briarcliff Manor, New York 10510
(914) 333-9650
jack.e.haken@philips.com

AMICUS
CURIAE
BRIEF

RECORD
AND
BRIEFS

Supreme Court, U.S.
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No. 12-1128

In The
Supreme Court of the United States

MEDTRONIC, INC.,

Petitioner,

v.

BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, AND MIROWSKI FAMILY VENTURES, LLC,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF OF LEGAL SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

Michael Simons
Counsel of Record
AKIN GUMP STRAUSS
HAUER & FELD LLP
300 West 6th Street
Suite 1900
Austin, TX 78701
(512) 499-6200
msimons@akingump.com

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

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Law Library

QUESTION PRESENTED

In *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 137 (2007), this Court ruled that a patent licensee that believes that its products do not infringe the patent and accordingly are not subject to royalty payments is "not required[] *** to break or terminate its *** license agreement before seeking a declaratory judgment in federal court that the underlying patent is *** not infringed."

The question presented is whether, in such a declaratory judgment action brought by a licensee under *MedImmune*, the licensee has the burden to prove that its products do not infringe the patent, or whether (as in all other patent litigation, including other declaratory judgment actions), the patentee must prove infringement.

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In The
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No. 12-1128

MEDTRONIC, INC.,
Petitioner,
v.

BOSTON SCIENTIFIC CORPORATION, GUIDANT CORPORATION, AND MIROWSKI FAMILY VENTURES, LLC,
Respondents.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF LEGAL SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF *AMICI CURIAE*[1]

Amici curiae are law professors and include scholars of administrative law, civil procedure, or intellectual property law who are interested in the efficient functioning of the United States patent system in the service of the public interest. They are filing this brief in their personal capacities. The views expressed herein represent their individual views and are not intended to represent those of their states, educational institutions, or any of those institutions' administrative subdivisions.

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[1] No counsel for a party "authored th[is] brief in whole or in part," and no such counsel or party "made a monetary contribution intended to fund the preparation or submission of th[is] brief," Sup. Ct. R. 37.6. In accordance with Supreme Court Rule 37.3(a), the parties have consented in writing to the filing of this brief.

The names of *amici curiae* for this brief are listed below. Institutional affiliations are included for purposes of clear identification.

Margo A. Bagley
Professor of Law
University of Virginia School of Law

Jorge L. Contreras
Associate Professor
American University – Washington College of Law

Thomas F. Cotter
Briggs and Morgan Professor of Law
University of Minnesota Law School

Christopher A. Cotropia
Professor of Law
University of Richmond School of Law

Rochelle C. Dreyfuss
Pauline Newman Professor of Law
New York University School of Law

John M. Golden
Loomer Family Professor in Law
The University of Texas at Austin

Timothy R. Holbrook
Associate Dean of Faculty and Professor of Law

Emory University School of Law

Jay P. Kesan
Professor and H. Ross and Helen Workman Research Scholar
University of Illinois College of Law

Gregory N. Mandel
Associate Dean for Research and Peter J. Liacouras Professor of Law
Temple University Beasley School of Law

Xuan-Thao Nguyen
Professor of Law
SMU Dedman School of Law

Charles M. Silver
Roy W. & Eugenia C. McDonald Endowed Chair in Civil Procedure
The University of Texas at Austin

INTRODUCTION

This case poses the question of how a burden of persuasion—often simply called a "burden of proof"[2]—should be assigned in a so-called mirror-image declaratory judgment suit, a suit in which "the positions of the plaintiff and defendant are transposed" relative to more traditional suits for coercive or compensatory relief. James W. Moore, MOORE'S FEDERAL PRACTICE § 57.62[2][c], at 57-134 (3d ed. 1997). In the opinion below, the United States Court of Appeals for the Federal Circuit acknowledged "the general proposition that mere role reversal in a declaratory judgment action does not shift the burden." Pet. App. 11a. Nonetheless, the Federal Circuit held that, "as a consequence of [this] Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007)," Pet. App. 8a, there is an exception to this "general proposition." Specifically, the Federal Circuit held that, "in the limited circumstance when an infringement counterclaim by a patentee is foreclosed by the continued existence of a license, a licensee seeking a declaratory judgment of noninfringement and of no consequent liability under the license bears the burden of persuasion." Pet. App. 14a.[3]

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[2] Consistent with common practice, this brief will sometimes use the term "burden of proof" to signify "burden of persuasion," the particular type of burden at issue in this case. More generally, the term "burden of proof" can encompass burdens of production. 2 Charles T. McCormick, MCCORMICK ON EVIDENCE § 336, at 644-45 (Kenneth S. Broun ed., 7th ed. 2013).

The Federal Circuit's holding did not disturb the burdens of persuasion applicable in most patent cases involving a claim for declaratory relief—*i.e.*, those featuring a claim for enforcement by a patent holder in a complaint or counterclaim. *See* K. Moore, T. Holbrook & J. Murphy, PATENT LITIGATION AND STRATEGY 52 (4th ed. 2013). According to the Federal Circuit, "[i]t is, of course, well settled that a patentee who files a complaint or counterclaim alleging patent infringement bears the burden of proving that infringement." Pet. App. 10a.

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[3] Technically, applicable licensing agreements mean that the relevant proof is of patent "claim coverage," rather than "infringement," but, in context, the term "infringement" seems adequately clear. See Br. in Opp'n 2 & n.1.

There are other propositions regarding declaratory plaintiffs' burdens of persuasion that are not at issue here. First, there is the requirement that a declaratory judgment plaintiff prove the existence of declaratory-relief jurisdiction—for example, by showing that there is an Article III "case or controversy." MOORE'S FEDERAL PRACTICE, *supra*, § 57.62[1], at 57-130. Also not at issue is the proposition that a declaratory-judgment plaintiff bears the burdens of persuasion that it would bear in a more traditional enforcement suit, such as the burden of proving an affirmative defense. *See James River Ins. Co. v. Kemper Cas. Ins. Co.*, 585 F.3d 382, 385 (7th Cir. 2009) (Posner, J.).

In mirror-image declaratory judgment cases like this one, the difficulty arises for issues, like patent infringement, on which, in a more traditional enforcement suit, the party seeking coercive or compensatory relief would have borne the burden of persuasion. In this situation, two oft invoked but here competing principles conflict. First, there is the principle that, consistent with the goal of rights clearance under the Declaratory Judgment Act, mirror-image declaratory-judgment actions should enable definitive resolution of the same legal question that would apply in more traditional rights-enforcement proceedings. *See Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 241 (1937). Second, there is the "view that the party who institutes an action *** should carry the burden." 10B C. Wright, A. Miller & M. Kane, FEDERAL PRACTICE AND PROCEDURE § 2770, at 679 (3d. ed., 1998). Faced with these conflicting principles, courts have come to different conclusions. *See id.* at 677-78; MOORE'S FEDERAL PRACTICE, *supra*, § 57.62[2][c], at 57-134. This brief substantially leaves to the parties and other *amici* the task of parsing these court decisions, many of which involve insurance litigation. Instead, the brief focuses on reasons why purposes and policy concerns specific to the Declaratory Judgment Act and Patent Act favor finding that the Federal Circuit's special rule for licensee declaratory judgment actions is unnecessary and inappropriate.

SUMMARY OF ARGUMENT

By placing a burden of proving noninfringement on a patent licensee who brings a declaratory judgment action, the Federal Circuit's holding below undercuts strong public interests in rights clearance that both the Declaratory Judgment Act and the Patent Act are meant to advance. In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), this Court recently confirmed a patent licensee's ability to bring a declaratory judgment action challenging the validity or scope of patent claims that it has licensed. The Federal Circuit's holding discourages pursuit of the very declaratory judgment actions that *MedImmune* enabled.

This discouragement occurs because the discrepancy between burdens in declaratory judgment and enforcement actions gives licensees greater relative reason either simply to accede to patent holders' assertions of infringement or to breach their contracts and wait to be sued in enforcement actions where the patent holder will need to prove infringement. Consequently, the Federal Circuit's holding fosters the sort of dilemma—choosing between capitulation to an alleged right holder and subjection to risk of an enforcement suit—that the Declaratory Judgment Act was meant to mitigate. *MedImmune*, 549 U.S. at 129.

Discouraging licensees from making declaratory judgment challenges to patent rights implicates public interests that the Declaratory Judgment and Patent Acts are intended to advance. As indicated above, this Court has recognized that a central purpose of the Declaratory Judgment Act is to enable the achievement of greater and more timely certainty about the scope and validity of others' rights. By helping to define the limits of others' rights, this certainty can provide private parties with a form of "clearance" to engage in socially productive activities.

This Court has also recognized that licensee declaratory judgment actions can further the Patent Act's purpose to promote scientific and technological progress, U.S. CONST. Article I, § 8, cl. 8. Generally speaking, the public has an interest in declaratory judgment actions that prove patent claims invalid or otherwise unenforceable, or that clearly establish that certain activities or products lie outside a patent's scope. In *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969), the Court observed that "[l]icensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery." When this is true, licensee challenges can be particularly vital to rights clearance that serves the public interest.

On the other hand, assigning a burden of proving noninfringement to patent licensees will complicate already difficult problems of patent case management and thereby threaten public interests in efficient and timely rights clearance. Patent cases are among the most time-consuming cases that judges hear, typically more time-consuming than even antitrust cases and voting rights cases. Assignment of the burden of persuasion on infringement to a patentee will complicate adaptation to declaratory judgment actions of local rules and orders for patent litigation that courts have developed for more traditional rights-enforcement suits. With respect to declaratory judgment litigation, the results could include forms of uncertainty, controversy, and waste bearing at least some relation to the ills that the Declaratory Judgment Act was meant to curtail.

Finally, in this particular case, fairness concerns do not weigh heavily in favor of the patent holder, Mirowski Family Ventures, LLC ("MFV)." Because MFV and Medtronic, Inc. entered contracts that explicitly contemplated the type of declaratory judgment brought here, MFV cannot claim undue surprise at being haled into court.

I. STRONG PUBLIC INTERESTS IN FACILITATING PATENT RIGHTS CLEARANCE FAVOR REQUIRING A PATENT HOLDER TO BEAR THE SAME BURDEN OF PERSUASION OF INFRINGEMENT IN A LICENSEE DECLARATORY JUDGMENT ACTION AS IN A COERCIVE SUIT FOR INFRINGEMENT.

The Federal Circuit's special rule for burdens of persuasion in licensee declaratory judgment actions conflicts with the purposes and intent of the Declaratory Judgment Act and undercuts strong public interests in rights clearance that were recently vindicated in *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118 (2007), the very decision to which the Federal Circuit's special rule responds.

A. Reference to Statutory Purpose, Context, and Related Policy Concerns Is Appropriate in Deciding the Allocation of Burdens of Persuasion in Declaratory Judgment Actions.

Statutory purposes and policies have a well-accepted role in informing the allocation of burdens of persuasion. *National Commc'ns Ass'n, Inc.* v. *AT&T Corp.*, 238 F.3d 124, 131 (2d Cir. 2001). In the absence of clear statutory direction, burdens of persuasion are commonly allocated after consideration of factors such as "(1) the natural tendency to place the burdens on the party desiring change, (2) special policy considerations such as those disfavoring certain defenses, (3) convenience,

(4) fairness, and (5) the judicial estimate of the probabilities." 2 McCormick, *supra*, § 337, at 652. Likewise, a number of courts and commentators have concluded that the test for how to allocate burdens of proof in declaratory judgment actions should be a flexible one, sensitive to a variety of factors such as the nature of the legal question, the nature of the remedy at issue, and "[w]hich party asserted the affirmative of the issue." MOORE'S FEDERAL PRACTICE, *supra*, § 57.62[2][c], at 57-134 - 57-135; *see also* Edwin Borchard, DECLARATORY JUDGMENTS 404-409 (2d ed. 1941) (analyzing judicial decisions on the "burden of proof" in declaratory judgment actions); *cf.* FEDERAL PRACTICE AND PROCEDURE, *supra*, § 2770 at 677-78 (noting "the weighty [view] of Professor Borchard").

In *Schaffer* v. *Weast*, 546 U.S. 49 (2005), which was not a declaratory judgment case but which the Federal Circuit's opinion cited prominently, Pet. App. 9a-10a, this Court reasoned in a manner consistent with the factors described above. The Court did acknowledge and make use of "the ordinary default rule that plaintiffs bear the risk of failing to prove their claims." *Schaffer*, 546 U.S. at 56. But the Court also observed that this "default rule, of course, admits of exceptions." *Id.* at 57. Moreover, the Court emphasized that, for "a statutory cause of action, the touchstone of our inquiry is, of course, the statute." *Id.* at 56. Accordingly, the Court examined the relevant statute's text, purpose, and structure, including evidence that Congress might not have desired an increase in "litigation and administrative expenditures" under the statute. *Id.* at 58-61. Only after such analysis did the Court hold that the category of plaintiffs at issue bore the contested burden of persuasion. *Id.* at 62.

B. Enabling "Mirror-Image" Suits to Clear Potential Legal Claims Is a Fundamental Purpose of the Declaratory Judgment Act.

A prime purpose of the federal Declaratory Judgment Act is to help eliminate uncertainty by enabling parties threatened with legal liability to obtain timely judicial determination of whether such liability applies. *See* H. Rep. No. 1264, 73d Congress, 2d Sess., at 2 (1934); S. Rep. No. 1005, 73d Congress, 2d Sess., at 2 (1934). Indeed, in *MedImmune*, a case in which this Court considered declaratory judgment jurisdiction in an action brought by a patent licensee, the Court described "the choice between abandoning [one's] rights or risking prosecution" as "'a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.'" 549 U.S. at 129 (quoting *Abbott Labs.* v. *Gardner*, 387 U.S. 136, 152 (1967)). This purpose of enabling timely "clearance" of others' rights reflects recognition that distortions in behavior resulting from lack of such clearance can harm not only the party fearing liability but also society as a whole. As a Senate committee recognized in 1934, through more timely resolution of disputes "much economic waste could be avoided, and social peace promoted." S. Rep. No. 1005, *supra*, at 3.

A key way the Declaratory Judgment Act facilitates rights clearance is through mirror-image declaratory judgment actions that enable parties threatened with legal liability to clarify the scope of others' rights without having to wait for a coercive or compensatory rights-enforcement suit. MOORE'S FEDERAL PRACTICE § 57.62[2][c], at 57-134. In *MedImmune*, this Court advanced the Declaratory Judgment Act's purpose of facilitating rights clearance by holding that a patent licensee need not breach its licensing agreement—and thereby subject itself to threat of an infringement suit—before bringing a mirror-image declaratory judgment action to clarify relevant patent claims'[4] validity, enforceability, or scope. *MedImmune*, 549 U.S. at 137.

C. Public and Private Interests in Rights Clearance Favor Requiring a Patent Holder to Bear the Burden of Proving Infringement in a Licensee Declaratory Judgment Action.

In light of the purposes and policies of the Declaratory Judgment Act and Patent Act, requiring proof of noninfringement by the plaintiff in a licensee declaratory judgment action is problematic in at least two ways. First, contrary to congressional intent, imposing that burden breaks intended symmetry between mirror-image declaratory judgment actions and counterpart enforcement actions. Second, this burden allocation reduces the value of the declaratory judgment action and thereby conflicts with congressional intent that the Declaratory Judgment Act foster timely rights clearance.

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[4] Patent claims are numbered clauses within the patent document that provide the primary definitions of what the patent covers. *See* John M. Golden, *Construing Patent Claims According to Their "Interpretive Community": A Call for an Attorney-Plus-Artisan Perspective*, 21 HARV. J.L. & TECH. 321, 322 (2008).

1. *Mismatch Between Burdens of Persuasion in Licensee Declaratory Judgment Actions and Counterpart Enforcement Actions Substantially Conflicts with the Intent That They Address the Same Legal Questions in Equally Definitive Manners.*

A mismatch between burdens of persuasion in declaratory judgment actions and more traditional enforcement actions can lead to different outcomes in mirror-image declaratory judgment actions and their counterpart enforcement actions. A court could determine that a declaratory judgment plaintiff had failed to prove *noninfringement* in a situation where the court would also have determined that a patent holder would have failed to prove *infringement*. In short, because of the burden-of-proof differential alone, the expected winner and effective result of a mirror-image declaratory judgment suit could differ from the winner and effective result of its counterpart enforcement suit.

One might argue that this mismatch between burdens and outcomes in mirror-image forms of suit is of predominantly only formal significance. With only a preponderance-of-the-evidence burden at stake, the fraction of cases falling into the state of limbo between provable infringement and provable noninfringement might be thought to be very small. *Cf. Schaffer*, 546 U.S. at 58.

The persistence with which the parties to this case have battled over allocation of the burden of persuasion, Pet. App. 4a-5a, suggests that the real-world stakes are larger than the above argument hypothesizes. But even a relatively small discrepancy in actual outcomes would sit uneasily with the sense expressed by this Court that the Declaratory Judgment Act quite generally permits "an immediate and definitive determination of the legal rights of the parties." *Aetna Life Ins. Co.*, 300 U.S. at 241. Interests in definitive rights clearance or non-clearance appear best served by declaratory judgment actions that involve precisely the same legal question—*e.g.*, "Can the patentee prove infringement?"—as would be decided in a more traditional enforcement action. *See* Restatement (Second) of Judgments § 28(4) (1982). Accordingly, a 1934 Senate committee report emphasized a statement by Representative Ralph Gilbert to the House that, in a declaratory judgment action, "'You have the same court, the same jurisdiction, the same procedure, the same parties[,] and the same question[s].'" S. Rep. No. 1005, *supra*, at 3 (quoting 69 Cong. Rec. 2030 (1928)).

Another reason to attach significance to the difference between requiring proof of infringement by a preponderance and requiring proof of noninfringement by a preponderance is the well-appreciated difficulty of proving a negative. Courts have long noted that, "all else *** being equal, courts should avoid requiring a party to shoulder the more difficult task of proving a negative." *National Commc'ns*, 238 F.3d at 131; *see* also *Newport News*

Shipbuilding & Dry Dock Co. v. *Director*, 592 F.2d 762, 765 (4th Cir. 1979) (noting that "the law rarely, if ever, imposes" "the burden of proving a negative fact" (internal quotation marks omitted)).

Difficulties with proving noninfringement of a patent might be a particularly good example of problems in proving a negative. A patent case can involve multiple patents, and each litigated patent can include many individual patent claims. Indeed, as a patent at issue in this case demonstrates, a single litigated patent can include hundreds of claims. *See* U.S. Reissue Pat. No. RE39,897, col. 7, l. 58, to col. 36, l. 65. In principle, infringement of each such claim might be separately asserted. Further, each asserted claim could have language that requires judicial interpretation, and a product or process accused of infringement can have multiple parts or aspects that might be argued to fulfill a particular patent claim requirement. A patent holder might have multiple theories for why each individual patent claim is infringed—including theories of literal infringement, infringement by equivalence, or infringement under alternate claim constructions. Under one theory, part *A* of the accused device might be argued to satisfy claim requirement *X*. Under another theory, part *B* of the accused device might be argued to satisfy that same claim requirement. Under another theory, a combination of parts *A* and *B* might play that role. In short, the familiar unwieldiness associated with demanding proof of a negative appears likely to result from requiring a declaratory judgment plaintiff to prove noninfringement as opposed to, say, showing "an absence of evidence" for infringement—the sort of burden that this Court held appropriate for obtaining summary judgment when the burden of persuasion was on the nonmoving party, *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 325 (1986).

The special difficulties involved with proving a negative could make the shifting of a preponderance-of-the-evidence burden on infringement from the patent holder to a patent licensee much more significant than it might at first seem. Prevailing on infringement against a patent holder in a declaratory judgment action could become substantially more difficult than prevailing on infringement against a patent holder in a more traditional enforcement action. Moreover, the resulting discouragement of declaratory judgment suits and accompanying rights clearance could be substantially enhanced if, as suggested in Section II.B below, courts hearing declaratory judgment suits cannot or do not readily adopt detailed case-management techniques along the lines of those already developed for more traditional enforcement actions. Plaintiffs might wisely steer clear of challenging patent rights through a form of litigation for which the district courts cannot hold out hope of relatively speedy and efficient adjudication. *Cf.* John M. Golden, *Patent Privateers: Private Enforcement's Historical Survivors*, 26 HARV. J.L. & TECH. 545, 607 (2013), available at http://jolt.law.harvard.edu/articles/pdf/v26/26HarvJLTech545.pdf.

2. *Placing on the Declaratory Judgment Plaintiff a Burden to Prove Noninfringement Reduces the Value of Declaratory Judgment Actions, Contrary to Public Interests in Rights Clearance.*

In accordance with the discussion in subsection I.C.1, allocation of a burden of proving noninfringement to a licensee declaratory judgment plaintiff will at least incrementally discourage licensees from bringing declaratory judgment actions. Placing such a burden on a declaratory judgment plaintiff will reduce the incentive to initiate a declaratory judgment action as opposed to either (1) abandoning any challenge to a patent holder's assertions of coverage and conforming to what the patent holder believes the license requires; or (2) breaching the contract and inviting a more traditional enforcement suit in which the patent holder, not the licensee, will bear the burden of proof on infringement. As this Court has repeatedly recognized, this pushing of the licensee toward "abandoning his rights" or a variant of "risking prosecution" is contrary to the spirit of the Declaratory Judgment Act because that dilemma is the one "'that it was the very purpose of the Declaratory Judgment Act to ameliorate.'" *MedImmune*, 549 U.S. at 129 (quoting *Abbott Labs.*, 387 U.S. at 152).

Putting aside general talk of legislative intent, however, is discouragement of some degree of timely rights clearance by imposing a burden of proving noninfringement on licensees really a bad thing?

One could make a formal argument that Congress thought so. As discussed in subsections I.C.1 and II.A, legislative history suggests that members of the Congress that enacted the Declaratory Judgment Act believed that, after a declaratory judgment suit's initiation, the suit would involve precisely the same procedures and substantive questions as would apply in a more traditional enforcement suit. If Congress embraced this view, Congress may be understood to have at least constructively decided that proper incentives to undertake rights clearance will result if the Declaratory Judgment Act generally enables parties to bring true mirror-image suits—*i.e.*, suits in which burdens of persuasion are allocated in the same way as in more traditional enforcement actions.

Moreover, there are more patent-specific reasons to believe that, if anything, challenges to patent rights' scope or validity need more encouragement, rather than less. The expense and risk of patent litigation, as well as the possibility of entering into an at least somewhat collusive arrangement with the patent holder, mean that private parties frequently have reason to license others' patents even when they have grave doubts about relevant patent claims' validity or applicability. *See* James Gibson, *Risk Aversion and Rights Accretion in Intellectual Property Law*, 116 YALE L.J. 882, 930 (2007); Golden, *Patent Privateers*, *supra*, at 616 & n.478. Further, there is often a substantial possibility that later-developed information—*e.g.*, a later-discovered prior art reference or development of a new technological approach that the licensee has greater reason to believe is not infringing—will give a licensee greater cause to challenge patent rights' validity or scope than existed at the time that a license was taken. One could respond, "Tough luck. You should have taken that possibility into account when you agreed to the license." But this Court's explicit allowance for declaratory-judgment actions to challenge licensed patent rights, *MedImmune*, 549 U.S. at 137, suggests that this Court has not accepted that such a "Tough luck" response should apply.

The public-goods nature of challenges to patent rights' validity or scope provides a general justification for rejecting the "Tough luck" approach. This Court has long recognized that court decisions in patent litigation can serve "a strong public interest" in clarifying the general public's, as well as a private litigant's, room to operate without fear of violating another's patent rights. *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993); *see also Lear, Inc.*, 395 U.S. at 670 ("Surely the equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain.").

As this Court recognized in *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730-731 (2002), the public interest in clarity extends to questions about patent claims' scope as well as patent claims' validity, and clarity about scope is "essential to promote progress"—the Patent Act's constitutional purpose. Like rulings on validity, rulings on claim construction and infringement can provide useful guidance to third parties about their freedom to operate. Under appropriate circumstances, rulings on patent scope can have preclusive effect in later proceedings and "make it trivial to avoid infringing the patent." Mark A. Lemley, *The Fractioning of Patent Law, in* INTELLECTUAL PROPERTY AND THE COMMON LAW 504, 510 n.32 (Shyamkrishna Balganesh ed., forthcoming 2013), *available at* http://ssrn.com/ abstract=1895681. Thus, for example, if *B* succeeds in winning a judgment that *A*'s patent on hand-held vacuums does not cover vacuums with a removable "restriction ring," *B*'s competitor *C* might also benefit substantially from the knowledge that it too can avoid the force of *A*'s patent by using a removable, rather than a permanently attached, "restriction ring." *See Toro Co.* v. *White Consol. Indus., Inc.*, 199 F.3d 1295, 1302 (Fed. Cir. 1999). Likewise, consumers might benefit from lower prices as a result of a court ruling that patent rights are narrower than previously thought, another benefit that the successful challenger of patent scope does not capture. *Cf.* Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 952-53 (2004).

In short, rulings that narrow a patent's apparent or potential scope—whether by invalidating a subset of a patent's claims, construing claim language, or determining that certain products or processes do not infringe—commonly benefit third parties as well as victorious challengers. The result is a classic public goods problem. Because challenges to patent rights produce positive externalities that the challengers do not capture, those challenges are commonly expected to be undersupplied relative to the social optimum. Golden, *Patent Privateers, supra*, at 616. By discouraging suit by patent licensees, whom this Court has identified as a critical class of potential declaratory judgment plaintiffs, *Lear*, 395 U.S., at 670 ("Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery."), assignment of the burden of persuasion on infringement to declaratory judgment plaintiffs like Medtronic would only make the expected undersupply of patent challenges worse.[5]

MFV ignores this effect on the public interest when it suggests that the burden of persuasion in a patent infringement dispute was effectively determined by contract provisions that explicitly provided for Medtronic's declaratory judgment action but that MFV has not contended specified any burden of proof that would apply in such an action. *See* Br. in Opp'n 14, 22, 24; JA 13, 20, 24. The present situation is thus like *MedImmune* in the sense that the patent holder argues that its contracts generate a limitation on vindication of public and private interests under the Declaratory Judgment Act, but the patent holder points to no explicit language in their contracts providing for that limitation—in this case, a requirement that the licensee shoulder a burden to prove noninfringement, whereas in *MedImmune* the alleged limitation had been a "prohibition against challenging the validity of the patents," 549 U.S. at 135.

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[5] Since 1980, Congress has repeatedly amended the Patent Act to provide opportunities to challenge patents in administrative proceedings. Golden, *Patent Privateers, supra*, at 613-14. But opportunities for administrative challenges are still significantly limited, and the major avenues only enable validity challenges and not challenges to assertions of infringement. *See* Janice M. Mueller, PATENT LAW, 96, 423, 432, 436 (4th ed. 2013) (noting limitation of post-grant review to challenges brought within nine months of patent issuance and limitation of reexamination and inter parts review to challenges based on prior-art patents or printed publications).

The special public interest in licensee declaratory judgment actions to challenge patents' validity or scope provides ample reason to be suspicious of arguments that the parties' contracts have effectively reallocated the burden of proof on infringement from where it would lie in a more traditional patent-enforcement action. Even when a private effort to shift burdens is confined to burdens of proof in contract disputes, courts have questioned private parties' power to contract to such an end. *See* Colter L. Paulson, *Evaluating Contracts for Customized Litigation by the Norms Underlying Civil Procedure*, 45 ARIZ. ST. L.J. 471, 511 (2013); *cf.* 20 Am. Jur. Evidence § 15 at 45 (1939). Here the Court considers a patent-infringement dispute, one implicating the public interest in testing the validity and scope of rights against the world that the Constitution and Congress have authorized, statute has structured, and a government body has issued. *See* U.S. CONST., Article I, § 8, cl. 8; 35 U.S.C. §§§ 101, 153 & 154(a).

II. INTERESTS IN EFFICIENT AND PREDICTABLE CASE MANAGEMENT PROVIDE FURTHER REASON FOR THE PATENT HOLDER TO BEAR THE BURDEN OF PROVING INFRINGEMENT IN A LICENSEE DECLARATORY JUDGMENT ACTION.

A. The History of the Declaratory Judgment Act Reflects Beliefs in the Procedural as Well as Substantive Congruence of Declaratory Judgment Actions and Counterpart Enforcement Actions.

The history of the Declaratory Judgment Act reflects a belief that there would be not only substantive but also procedural congruence between declaratory judgment actions and counterpart enforcement actions. Section I.C.1 noted Representative Gilbert's assertion, quoted by a Senate committee report, that declaratory judgment actions would involve "the same procedure, the same parties[,] and the same question[s]." S. Rep. No. 1005, *supra*, at 3 (quoting 69 Cong. Rec. 2030 (1928)).

This belief in congruence extending to procedure as well as substance appears to have had an effect on the actual language of the Act—or, more precisely, the lack of certain language in the Act. In 1928 Senate hearings, Professor Edson Sunderland—often credited alongside Professor Edwin Borchard with being a prime intellectual force behind the federal Declaratory Judgment Act, FEDERAL PRACTICE AND PROCEDURE, *supra*, § 2752, at 459—emphatically asserted an essentially perfect congruence between more traditional enforcement actions and declaratory judgment suits. In his words, "the only way you can tell whether a proceeding is a proceeding for a declaration or an ordinary proceeding" is through the prayer.[6] Hearings Before a Subcomm. of the Comm. on the Judiciary, U.S. Senate, 70th Cong. 31 (1928) [hereinafter "1928 Hearings"]. The target of Sunderland's testimony was a provision for Supreme Court rulemaking under the Act, a provision that Sunderland argued was misleading in that it "assume[d] the necessity or the advisability of special procedure, whereas special procedure is not either necessary or advisable," 1928 Hearings, *supra*, at 32. Congress acted in accordance with Sunderland's testimony. According to the 1934 Senate committee report, members of Congress struck from the ultimate Act the section about which Sunderland had complained and did so substantially for the reasons he asserted—namely, that "there is no necessity for rules, for there is no material change in existing procedure" outside the prayer, S. Rep. No. 1005, *supra*, at 5.

The apparent congressional intent for there to be precise procedural congruence, as well as substantive congruence, between declaratory judgment actions and rights-enforcement actions is important for two reasons. First, to the extent one views burdens of proof as at least partly procedural,

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[6] Professor Sunderland did not make this statement in ignorance of the likelihood of mirror-image suits: his testimony explicitly noted the possibility of mirror-image suits for clearance of patent rights. 1928 Hearings, *supra*, at 35.

cf. Robert G. Bone, *Party Rulemaking: Making Procedural Rules Through Party Choice*, 90 TEX. L. REV. 1329, 1333, 1350 (2012), this generalized congruence principle provides another reason to believe that allocation of the burdens of persuasion in declaratory judgment actions should be the same as in more traditional enforcement actions. Second, to the extent that a difference in the burdens of persuasion tends to generate procedural incongruities and complications, Congress' sense that these should not result from application of the Declaratory Judgment Act provides further reason to doubt the propriety of the difference in burdens of persuasion. As section II.B discusses, procedural complications are in fact a likely result of imposing a burden to prove noninfringement in licensee declaratory judgment actions.

B. As This Case Illustrates, the Federal Circuit's Special Rule for the Burden of Proof on Infringement in Licensee Declaratory Judgment Actions Will Complicate Already Difficult Problems of Patent Case Management.

Patent litigation tends to be complex and costly. In 2004, the Subcommittee on Judicial Statistics and Committee on Judicial Resources of the Judicial Conference of the United States approved a system of case weights reflecting "the judicial work required by cases of different types"—*i.e.*, "how much more or less time-consuming one type of case is compared to other cases." 2003-2004 District Court Case-Weighting Study: *Final Report to the Subcommittee on Judicial*

Statistics of the Committee on Judicial Resources of the Judicial Conference of the United States 1 (2005). With a case weight of 4.72, patent cases have the fourth highest case weight on a list of forty-two types of civil cases. *Id.* at 5 tab 1. Ranking ahead of case categories such as "Civil Rights: Voting" (case weight of 3.86) and "Antitrust" (case weight of 3.45), patent cases trailed only the case categories "Death Penalty Habeas Corpus" (case weight of 12.89), "Environmental Matters" (case weight of 4.79), and "Civil RICO" (case weight of 4.78). *Id.*

By discussing the possibilities for assertion of multiple patents, multiple claims within patents, and multiple theories of infringement for individual claims, subsection I.C.1 has indicated how patent cases can present case-management challenges. Those indications are not merely theoretical. For years, courts have engaged in efforts to provide tractable paths through the maze of assertions, counter-assertions, and associated fact gathering that a patent case can involve. Many district courts have adopted local rules or standing orders specifically for patent litigation. P. Menell, *et al.*, PATENT CASE MANAGEMENT JUDICIAL GUIDE 2-8 to 2-9 (2009) [hereinafter "Patent Case Management"]. A number of district courts have severely limited the numbers of claims or disputed claim terms on which parties can seek rulings at any given time. *See id.*, at 5-8 (discussing Northern District of California rules that "limi[t] to ten the number of claim terms that will be construed in the *Markman* proceeding"); Dianne Brown Elderkin & Domingo Manuel Llagostera, *Case*

Management Issues in Patent Infringement Litigation, 13 SEDONA CONF. J. 77, 89-91 (2012).

District courts have commonly required the patent holder to elect the claims on which to move forward. *See* Elderkin & Llagostera, *supra*, at 88-91. Placement on the patent holder of primary responsibility for clarifying and streamlining the case on infringement comports with the sense behind an argument for not assigning to an accused infringer a burden of proving noninfringement—namely, that it can be difficult to prove a "negative." *See supra* Section I.C.1. Requiring a declaratory judgment plaintiff to explain how a required patent claim element is absent from an accused product seems less likely to generate useful information than requiring the patent holder to specify which particular aspects of the accused product satisfy each of the limitations of asserted claims.[7]

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[7] Under the "All Elements Rule" for infringement, a patent claim is infringed only if every limitation in the claim (sometimes referred to as a "claim element") has at least an equivalent in the accused product or process—*i.e.*, only if every limitation in the claim appears in the accused product or process either literally or under the doctrine of equivalents. Janice M. Mueller, PATENT LAW *supra*,. Hence, patent holders commonly must support infringement contentions with an analysis of each asserted patent claim that indicates how each limitation of each claim appears literally or by equivalence in an accused device or process. *See* K. Moore, T. Holbrook & J. Murphy, PATENT LITIGATION AND STRATEGY 212-13 (4th ed. 2013). Patent holders often satisfy such requirements by providing spreadsheet-like claim charts that indicate theories of infringement and explicitly associate each portion of an asserted claim's language with specified aspects of accused devices or processes. *Id.*; *cf.*

To be sure, by manipulating burdens of production or other tools of case management, courts can overcome hurdles to effective case management presented by awkward assignment of the burden of persuasion. But as the present case indicates, the uncertainty and cost incurred while courts advance toward such a happy result are unlikely to be trivial.

This case's dispute over allocation of a burden of persuasion came to a head with petitioner Medtronic's pretrial motion to "preclude Dr. Berger, defendant[] [MFV's] expert on infringement, from testifying because 'he failed to map every element of each asserted claim against the accused Medtronic devices in his expert report.'" Pet. App. 41a. MFV responded to this motion by contending that, because it did not bear the burden of proving infringement, such element-by-element analysis was not required. Pet. App. 44a n.10; *see also* Pet. App. 5a.

Disputes such as those over the adequacy of parties' pretrial contentions have long plagued the district courts. Indeed, they have been a prime motivation for the adoption of local patent rules that provide substantial, standardized governance for a suit's pretrial period. Patent Case Management, *supra*, at 4-14; *see also O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1365-66

Genentech, Inc. v. Amgen, Inc., 289 F.3d 761, 773 (Fed. Cir. 2002) (upholding order barring Genentech "theory of infringement under the doctrine of equivalents because Genentech did not expressly include that theory in a claim chart").

(Fed. Cir. 2006) (upholding local patent rules requiring "early notice of [parties'] infringement and invalidity contentions").

As this case demonstrates, reallocating a burden of persuasion is a surefire way to generate new barrages of disputes over the adequacy of contentions. The Federal Judicial Center's publication, Patent Case Management Judicial Guide, indicates that "understanding the parties' respective burdens" has been crucial to such disputes' resolution. Patent Case Management, *supra*, at 4-14. In this very case, the Federal Circuit signaled that allocation of the burden of persuasion can substantially inform judicial resolution of such a dispute. In response to "MFV's argument that Medtronic's interrogatory responses effectively conceded that all unaddressed claim limitations were satisfied," the Federal Circuit stated:

> "Because Medtronic, and ultimately the district court, did not appreciate the appropriate allocation of the burden of proof and how the burden affected the parties' conduct during discovery, it is within the district court's discretion on remand whether to limit Medtronic to its current interrogatory answer, or to allow Medtronic to amend its interrogatory answer to include any additional noninfringement contentions it may wish to assert."

Pet. App. 15a.

In short, allocating the burden of persuasion on infringement to licensees such as Medtronic can be expected to trigger an extended series of disputes over the adequacy of parties' contentions or other pretrial submissions. Parties and courts will need to determine whether and how pretrial rules for licensee declaratory judgment actions should differ from those for other types of patent-infringement actions. No doubt, the district courts can resolve the resulting disputes. One can hope that the district courts can ultimately provide a set of resolutions that brings reasonable levels of predictability and efficiency to licensee declaratory judgment actions. In the meantime, however, there will be uncertainty, controversy, and waste, variants of the very causes of social harm that the Declaratory Judgment Act was meant to curtail.

III. ANY GENERAL FAIRNESS CONCERNS IN FAVOR OF PLACING THE BURDEN OF PERSUASION ON THE PLAINTIFF ARE MUTED WHERE, AS HERE, THE PARTIES' AGREEMENTS EXPLICITLY PROVIDE FOR THE BRINGING OF A LICENSEE DECLARATORY JUDGMENT ACTION.

Courts have considered fairness to be a concern in allocating burdens of persuasion. 2 McCormick, *supra*, § 337, at 652. The Federal Circuit arguably incorporated fairness concerns in its rationale below by basing that holding in part on its view that the petitioner Medtronic is the party seeking "to disturb the status quo ante." Pet. App. 13a. Such attention to who seeks to disrupt the status quo comports with the notion that burdens of persuasion are commonly assigned to the plaintiff because it is "the plaintiff who generally seeks to change the present state of affairs." 2 McCormick, *supra*, § 337, at 648. In this case, however, the nature of the relevant "status quo ante" is ambiguous at best. At the very least, MFV cannot claim any undue surprise at being haled into court.

Medtronic brought this declaratory judgment action in accordance with express provisions for future dispute resolution in the parties' contracts, which explicitly provided for Medtronic to bring a declaratory judgment action against MFV. JA 13, 20, 24. Further, under the dispute resolution regime outlined by the parties, one might contend that MFV, not Medtronic, disturbed any relevant "status quo ante" by providing notice of MFV's contentions that new Medtronic products fall within the scope of MFV's patents. Pet. App. 4a; JA 37. MFV's provision of notice altered the status quo in the sense that it triggered Medtronic's contractual obligation to pay royalties and to preserve any dispute by filing a declaratory judgment challenge within 90 days. JA 28-29.

Arguably, however, the more fundamental truth is that, in pursuing this dispute, neither party has disturbed or sought to disturb the relevant status quo because both parties have simply acted in accordance with their agreed regime for dispute resolution. Under this view, there is no relevant disruption that will result from a declaratory judgment in favor of Medtronic. Instead, there will simply be resolution of a disagreement that the parties' contracts anticipated, with that resolution having been achieved by the means for resolution that their contracts provided.

This final viewpoint resonates strongly with the purposes for which the Declaratory Judgment Act was adopted. As conceived by declaratory judgments' great champions, Borchard and Sunderland, declaratory judgments were intended as vehicles for "preventive justice," potentially operating simply to clarify legal aspects of an existing status quo in a way that helped avoid disruption. Edwin M. Borchard, *The Declaratory Judgment—A Needed Procedural Reform*, 28 YALE L.J. 105, 110 (1918), *reprinted in* Edwin M. Borchard, Brief Submitted to the Committee on the Judiciary, United States Senate, 65th Cong. 30 (Comm. Print 1919); *see also* S. Rep. No. 1005, *supra*, at 6 ("It enables disputes *** to be adjudicated without requiring a destruction of the status quo and of the social and economic fabric."); Edson R. Sunderland, *A Modern Evolution in Remedial Rights—The Declaratory Judgment*, 16 MICH. L. REV. 69, 76 (1917) ("It makes the law suit a coöperative proceeding, in which the court merely assists the parties to settle their own differences by stating to them the rules of law which govern them.").

In short, ambiguity about the relevant "status quo ante" and attending fairness concerns might be endemic to declaratory judgment actions. Moreover, given the parties' contracts, that ambiguity seems particularly strong here.

CONCLUSION

The foregoing provides reasons favoring a ruling that, in a declaratory judgment action brought by a licensee to challenge the scope of licensed patents, the patent holder bears the burden of persuasion on infringement even when, as in this case, the patent holder cannot bring a counterclaim for infringement.

Respectfully submitted.

Michael Simons
Akin Gump Strauss
 Hauer & Feld LLP

August 2, 2013

AMICUS CURIAE BRIEF

SUPREME COURT, U.S.
FILED

AUG 2 - 2013

OFFICE OF THE CLERK

No. 12-1128

In The
Supreme Court of the United States

◆

MEDTRONIC, INC.,

Petitioner,

v.

BOSTON SCIENTIFIC CORPORATION,
GUIDANT CORPORATION, AND
MIROWSKI FAMILY VENTURES, LLC,

Respondents.

◆

**On Writ Of Certiorari To The
United States Court Of Appeals
For The Federal Circuit**

◆

BRIEF OF TESSERA TECHNOLOGIES, INC. AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY SUGGESTING VACATUR AND REMAND ON SUBJECT-MATTER JURISDICTIONAL GROUNDS

◆

RENEE DUBORD BROWN
TESSERA TECHNOLOGIES, INC.
3025 Orchard Parkway
San Jose, CA 95134
(408) 321-6000

ROMAN MELNIK
Counsel of Record
KENNETH WEATHERWAX
NATHAN N. LOWENSTEIN
FLAVIO M. ROSE
GOLDBERG, LOWENSTEIN
& WEATHERWAX LLP
11400 W. Olympic Blvd.,
Ste 400
Los Angeles, CA 90064
(310) 307-4500
melnik@glwllp.com

August 2, 2013

Counsel for Amicus Curiae Tessera Technologies, Inc.

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

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INTEREST OF THE *AMICUS CURIAE*

Amicus curiae Tessera Technologies, Inc. ("Tessera") is a leading provider of miniaturization technologies for the electronics industry. Tessera and its affiliates presently have over 1,463 issued United States patents, over 559 pending United States patent applications, and more than twenty licensees in the area of semiconductor chip packaging technology, including the world's top component companies such as Intel, Samsung, SK hynix, Sharp, Toshiba and Texas Instruments.

Tessera's continuing innovation depends on its ability to license its technology and enforce its license agreements. Consequently, Tessera's interest in this matter is twofold. First, as a frequent licensor, it has an obvious interest in the burden of persuasion question at issue on the merits. But second, and more importantly, Tessera seeks to fulfill a quintessential *amicus curiae* role by calling to the Court's attention jurisdictional issues overlooked by the parties.[1]

◆

SUMMARY OF ARGUMENT

This Court has granted *certiorari* to determine who has the burden of persuasion when a non-repudiating licensee seeks a declaration that because its products do not infringe certain licensed patents, they do not fall within the scope of a patent license agreement and thus do not trigger a royalty payment obligation. The Court should not reach the merits of this question for two independent reasons.

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[1] No person other than Tessera and its counsel made a monetary contribution to the preparation or submission of this brief, or authored any part of it. The parties have consented to this filing; the consents are on file with the Court.

First, because the district court lacked exclusive federal question patent jurisdiction in this case, the Federal Circuit lacked appellate jurisdiction. The parties had established a comprehensive contractual royalty dispute resolution procedure that permitted the licensee to file a *nested* declaratory judgment action of noninfringement, invalidity and unenforceability while maintaining its license and escrowing contested royalties, and to obtain a refund if it prevailed. Consequently, the licensee did not, when it filed this action, face the usual choice between, on the one hand, continuing to pay royalties while litigating and risking inability to recoup those payments, and, on the other, ceasing to pay royalties and risking termination of the license and subsequent freestanding patent litigation entailing potentially far greater damages and injunctive relief. Because there was simply no chance that the licensee suddenly would abandon the contractual dispute resolution procedure after nearly twenty years when it could resolve the very same patent issues within the contractual framework, and when both licensed patents were, in any event, set to expire within a year, a coercive patent infringement action by the licensor cannot reasonably be said to have been anticipated or threatened at the time of the initial filing. Consequently, exclusive federal question patent jurisdiction cannot be established on that basis. Nor can the licensor's potential contractual coercive action (asserting that because the licensee's products infringed the licensed patents and thus fell within the scope of the license, royalties were owed and should have been paid over to the licensor rather than into escrow) provide a basis for exclusive federal question patent jurisdiction in view of *Gunn v. Minton*, 555 U.S. ___, ___, 133 S.Ct. 1059, 1066-68 (2013). Thus the Federal Circuit's judgment should be vacated, and the case remanded with instructions to transfer the appeal to the Third Circuit.

Second, even assuming, *arguendo*, that the latter type of federal question jurisdiction properly was invoked in this case notwithstanding *Gunn*, vacatur and remand nonetheless are appropriate. Under this Court's long-standing precedents, the burden of persuasion is substantive for vertical-choice-of-law purposes. Because the question of whether certain products fall within the scope of a patent license, and thus incur a royalty payment obligation, is, under *Lear, Inc. v. Adkins*, 395 U.S. 653, 661-62 (1969), a matter of state law – even when the scope of that license is defined in terms of noninfringement – the burden of persuasion on that issue also ordinarily is a matter of state law. Remand therefore is necessary for the lower courts to consider, in the first instance, whether the parties contracted out of the default state-law rule as a consequence of the choice-of-law clauses they included in their agreements, and, if they did not, what the allocation of the burden of persuasion would be under the applicable state law.

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ARGUMENT

I. BECAUSE THE DISTRICT COURT LACKED FEDERAL QUESTION JURISDICTION UNDER 28 U.S.C. §1338(a), THE FEDERAL CIRCUIT LACKED APPELLATE JURISDICTION

It is axiomatic that this Court has an independent obligation to examine both the basis for its own subject-matter jurisdiction, and that of the courts below. *See, e.g.*, *Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 541 (1986). The parties and the lower courts in this matter proceeded on the assumption that subject-matter jurisdiction properly was invoked in the district court based on the existence of a federal question under 28 U.S.C. §§ 1331 and 1338(a).[2] Pet. App. 22a. That assumption, for the reasons that follow, was incorrect. In the absence of exclusive federal question patent jurisdiction under §1338(a) in the district court, the Federal Circuit lacked appellate jurisdiction under 28 U.S.C. §1295(a)(1).[3] *See Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807 (1988). Consequently, the Federal Circuit's judgment should be vacated, and the case remanded with instructions to transfer the appeal to the Third Circuit to determine whether another jurisdictional basis in the district court, such as diversity, existed, and to decide the appeal on the merits if it did.

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[2] Section 1331 provides that the "district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States."

Section 1338(a) provides, in relevant part, that the "district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents . . . ." and that "[n]o State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents . . . ."

A. The District Court Lacked Exclusive Federal Question Subject-Matter Jurisdiction

A district court's exclusive federal question jurisdiction under 28 U.S.C. §1338(a) can properly be invoked in one of two ways.[4] The first and most common category, which this brief calls "**Type-1**," is one where "federal law creates the cause of action asserted."

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[3] The version of section 1295(a)(1) that applies to this case provided, in relevant part, that "the Federal Circuit shall have exclusive jurisdiction . . . of an appeal from a final decision of a district court . . . if the jurisdiction of that court was based, in whole or in part, on section 1338."

[4] It is unnecessary separately to discuss subject-matter jurisdiction under §1331 in view of this Court's observation that "adhering to the demands of linguistic consistency, we have interpreted the phrase 'arising under' in both sections identically, applying our §1331 and §1338(a) precedents interchangeably." *Gunn*, 133 S.Ct. at 1064 (quotation marks and alterations omitted). If jurisdiction is absent under §1338(a), it is necessarily also absent under §1331.

Gunn, 133 S.Ct. at 1064. The second "special and small category of cases," which this brief calls "**Type-2**," is one in which, under certain circumstances, "arising under jurisdiction still lies" despite the fact that the claim asserted "finds its origins in state rather than federal law." *Id.* at 1064-65 (quotation marks omitted).

In suits brought under the Declaratory Judgment Act, such as the one here, the existence of either Type-1 or Type-2 federal question subject-matter jurisdiction may, in turn, be demonstrated in one of two ways. With respect to those counts of the complaint that seek "'in essence to assert a [federal] defense to an impending or threatened'" action, "'it is the character of the threatened action, and not of the defense, which will determine whether there is federal-question jurisdiction in the District Court.'" *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 16 & n.14, 19 (1983) (quoting *Pub. Serv. Comm'n of Utah v. Wycoff Co.*, 344 U.S. 237, 248 (1952) ("*Wycoff*")). With respect to those counts of the complaint that seek affirmative relief, on the other hand, the jurisdictional inquiry applies directly. *See Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 672 (1950); *see also* 10B Charles A. Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure §2767 at 650 (3d ed. 1998 & Supp. 2013) ("The complaint in a declaratory judgment action may be judged on its own merits; if it reveals a federal claim, then jurisdiction will exist. . . . The alternative is to say that the declaratory action may be entertained in federal court only if the coercive action that would have been necessary, absent the declaratory-judgment procedure, might have been so brought.").

Our analysis therefore must begin with an examination of Medtronic's declaratory judgment complaints. In order to understand the nature of those pleadings, however, it is first necessary to consider the parties' various license agreements.

1. The Parties' Agreements And The Contractual Nature Of Medtronic's Declaratory Judgment Complaints

a. The Parties' Agreements Created A Contractual Royalty Dispute Resolution Procedure With Nested Determination Of Patent Issues

The licensing relationship between Medtronic and Mirowski Family Ventures, LLC ("MFV") is governed by several key agreements – the 1991 License Agreement ("1991 License") (JA7-18), the various 2003 Letter Agreements, and the 2006 Litigation Tolling Agreement ("LTA") (JA19-29). *See also Medtronic, Inc. v. Boston Scientific Corp.*, 587 F. Supp. 2d 648, 651-53 (D. Del. 2008) ("*Medtronic I*") (describing agreements).

Under these agreements, MFV must identify the claims of the licensed patents that it believes are infringed by any new Medtronic products so as to fall within the scope of the license and trigger a royalty payment obligation. JA13; JA23-24 (§7(c)). If

Medtronic disagrees, it has the right, "while maintaining its sublicense under the License Agreement, . . . to challenge the validity and enforceability of any patent under the Mirowski license . . . [and the] assertion of infringement of any of the Mirowski patents through a Declaratory Judgment action." JA13; *see also* JA20; JA24 (§8). During the course of any such declaratory judgment litigation, Medtronic also has the right to escrow contested royalties, and may obtain a complete or partial refund of such royalties if it prevails in whole or in part. JA13; JA19; JA27-28 (§§ 10(a) & 11).[5] MFV, on the other hand, is contractually prohibited, in any such declaratory judgment proceeding, from requesting damages, treble damages, or injunctive relief against Medtronic; only contractual royalties may be sought. JA13.[6] Finally, the agreements contain two claim preclusion clauses. If MFV fails to follow the specified contractual procedures for identifying Medtronic products, no royalty is owed even if noninfringement by such products of the licensed patents is never actually litigated. JA23-24 (§7(c)). Conversely, those products with respect to which Medtronic fails to follow the specified contractual procedures become subject to the royalty obligation without further adjudication. JA24 (§8).

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[5] *See also Medtronic I*, 587 F. Supp. 2d at 652, 653 & n.8, 657.

[6] *See also* JA13 ("In any such litigation, if Medtronic is found not to have any royalty obligations with respect to the products in dispute then it shall be considered the winning party."); *Medtronic I*, 587 F. Supp. 2d at 657 ("If Medtronic wins, it can recover the portion of the escrow corresponding to noninfringing products. If MFV wins, Medtronic must continue to pay royalties. . . . No damages are contemplated. Even if MFV had initiated the present action, it would seek only to compel royalties due under the parties' contract.").

These provisions, taken together, make clear that the parties have established a comprehensive and *contractual* royalty dispute resolution procedure that permits *nested* determination of all relevant patent issues under the aegis of their agreements while affording Medtronic privileges that it would not, or at least may not, possess in conventional patent litigation. Under Federal Circuit precedent, declaratory judgment plaintiff-licensees have no right to escrow royalties,[7] and their right to recoupment of any royalties paid during the course of the litigation is unclear.[8] Additionally, in conventional patent litigation, damages, enhanced damages, and injunctive relief are, of course, available in appropriate cases. *See* 35 U.S.C. §§ 283 & 284. Finally, under Federal Circuit precedent, noninfringement claim preclusion does not attach as a matter of course to products that were not at issue in a prior case.[9] The parties' dispute resolution procedure therefore envisions litigation about patent issues connected to the royalty obligation that differs dramatically both from patent litigation between parties with no prior contractual relationship, and from the overwhelming majority of patent disputes between licensees and licensors.

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[7] *See Cordis Corp. v. Medtronic, Inc.*, 780 F.2d 991, 995 (Fed. Cir. 1985).

[8] *See Intermedics Infusaid, Inc. v. Regents of the Univ. of Minn.*, 804 F.2d 129, 133 (Fed. Cir. 1986) (describing issue as unsettled); *see also Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997) ("[A] licensee . . . cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid.").

b. The Declaratory Complaints Are Contractual In Nature

Medtronic's declaratory judgment complaints are directed to the parties' special contractual dispute resolution procedure, and do not purport to initiate conventional freestanding patent litigation.[10]

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[9] *See Acumed LLC v. Stryker Corp.*, 525 F.3d 1319, 1324-26 (Fed. Cir. 2008).

[10] Medtronic filed an initial Complaint in this action on December 17, 2007, followed by a First Amended Complaint on November 5, 2008. JA1 (Dkt. 1); JA34-36; Pet. App. 21a (Dkt. 84). On January 23, 2009, both of the licensed patents at issue expired. Pet. App. 30a; Pet. Br. 13 n.6. Medtronic then filed a superseding Second Amended Complaint on February 10, 2009. JA1 (Dkt. 108); JA40-46.

The question of which of these pleadings is the jurisdictionally-relevant one is discussed in Section I.A.3.iii., *infra*. For now, both the initial and the Second Amended Complaints are described together.

The parties' Joint Appendix does not reproduce these pleadings in full. Consequently, where necessary, Tessera has cited to the original documents in the record. The First Amended and

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The complaints recite the existence of the various license agreements;[11] note that MFV has identified certain Medtronic "Accused Devices" pursuant to the procedure in those agreements as allegedly infringing certain "Asserted Claim[s]" of the licensed patents so as to trigger a royalty payment obligation;[12] and conclude that "[u]nder the terms of the [LTA], the parties agreed that . . . after receiving notice of infringement from Mirowski . . . , Medtronic may initiate a Final DJ action . . . , challenging infringement, unenforceability and/or validity of the [licensed patents]." JA42 (¶25); JA36 (¶23).[13] The Initial Complaint concludes with two counts seeking a declaratory judgment of noninfringement and two counts seeking a declaratory judgment of invalidity; the First and Second Amended Complaints add two counts seeking a declaratory judgment of unenforceability.[14]

It is apparent, however, that what is really being sought is a declaration that because Medtronic's

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Second Amended Complaints also are available on Westlaw, at 2008 WL 5588205 and 2009 WL 1347257, respectively.

[11] *See* Second Amended Complaint ¶¶ 12 & 19; JA34-35 (¶¶ 12 & 19).

[12] *See* JA41 (¶15); Second Amended Complaint ¶20; *id.* ¶¶ 21-24 & 27-28 (partially JA41-42); Initial Complaint ¶¶ 15 & 20-22 & 25-26 (partially JA35-36).

[13] *See also* JA41 (¶15); Second Amended Complaint ¶29; JA35-36 (¶¶ 15 & 26).

[14] *See* Initial Complaint ¶¶ 24-25 & 27-40; First Amended Complaint ¶¶ 24-26 & 28-49; Second Amended Complaint ¶¶ 26-28 & 30-51 (partially JA42-45).

products do not infringe the licensed patents, they do not fall within the scope of the license agreements and thus do not trigger a royalty payment obligation, or, alternatively, that Medtronic may escape its royalty payment obligation because those licensed patents are invalid and/or unenforceable. *See Lear*, 395 U.S. at 661, 674 (royalty payment obligation may be avoided due to patent invalidity or, if the license so provides, noninfringement); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 122 n.1 & 135 (2007) (noting licensee's assertion "that the contract . . . does not require the payment of royalties because the patents do not cover its products and are invalid [and unenforceable]"). The noninfringement counts are directed solely to the "Accused Devices" identified by MFV pursuant to the contractual procedure as triggering a royalty payment obligation; the invalidity and unenforceability counts are, similarly, directed solely at the "Asserted Claim[s]" identified by MFV pursuant to the same procedure. Initial Complaint ¶¶ 24-25 & 27-40; Second Amended Complaint ¶¶26-28 & 30-51 (partially JA42-45). The requested noninfringement relief is phrased in the past and present continuous tense, seeking a "declaration that Medtronic has not infringed and is not infringing." Initial Complaint at 8 (¶1); JA45 (¶1). The complaints make no mention of any fear of future termination of the agreements if Medtronic were to cease payment of royalties, or any anticipation of freestanding patent litigation with exposure to damages, treble damages, or injunctive relief upon any such termination. (Of course, the Second Amended Complaint could not do so in any event, as the patents already had expired while the license was still in effect. Pet. Br. 13 n.6.)

With the contractual nature of Medtronic's declaratory complaints clearly in mind, we turn to the question of subject-matter jurisdiction.

2. Federal Question Jurisdiction Cannot Be Based Directly On Any Anticipatory Defenses Pled In The Complaints

As an initial matter, the counts seeking a declaration of invalidity and unenforceability cannot serve as a *direct* basis for federal question jurisdiction because each such count simply recites a federal defense. *See Christianson*, 486 U.S. at 809 ("[A] case raising a federal patent-law defense does not, for that reason alone, 'arise under' patent law, even if the defense is anticipated in the plaintiff's complaint. . . .") (quotation marks omitted). With respect to these counts, "'it is the character of the threatened action, and not of the defense, which will determine whether there is federal-question jurisdiction in the District Court.'" *Franchise Tax Bd.*, 463 U.S. at 16 & n.14, 19 (quoting *Wycoff*, 344 U.S. at 248).

Whether the counts seeking a declaration of noninfringement similarly are defensive in nature, or instead seek affirmative relief, is, of course, at the heart of the parties' dispute on the proper allocation of the burden of persuasion. There is no need to resolve this issue for jurisdictional purposes. To the extent that the noninfringement counts are viewed as defensive, they cannot serve as a *direct* basis for federal question jurisdiction for the same reason as the invalidity and unenforceability counts, and must be analyzed in the same way. To the extent that the noninfringement counts are viewed as seeking affirmative relief, their jurisdictional significance is discussed in Section I.A.3.b., *infra*.

3. The District Court Lacked Type-1 Federal Question Jurisdiction

a. The Threatened Coercive Actions Do Not Establish Type-1 Jurisdiction Over Any Defensive Count

We turn, next, to the question of what "'impending or threatened'" "coercive" actions by the declaratory judgment defendant MFV can be said to have been "anticipated" by the invalidity and unenforceability declaratory counts of Medtronic's complaints, and by the noninfringement counts to the extent that such counts are considered defensive. *Franchise Tax Bd.*, 463 U.S. at 16 n.14, 19 & n.19 (partially quoting *Wycoff*, 344 U.S. at 248).

This Court has observed that "federal courts have consistently adjudicated suits by *alleged patent infringers* to declare a patent invalid, on the theory that an infringement suit by the declaratory judgment defendant would raise a federal question over which the federal courts have exclusive jurisdiction." *Franchise Tax Bd.*, 463 U.S. at 19 n.19 (emphasis added). Suits brought by *patent licensees under an existing license*, however, seeking a declaration that the license agreement does not require payment of royalties because their products do not infringe the licensed patents and/or that the royalty payment obligation may be avoided because those licensed patents are invalid and unenforceable, have not proven amenable to such a straightforward *per se* rule in favor of federal question jurisdiction.

Rather, the Courts of Appeals consistently have emphasized that, in such cases, the jurisdictional analysis is highly fact-specific. Some decisions, *see* n.17, *infra*, have found Type-1 jurisdiction lacking because, *under the facts presented*, the sole coercive action threatened as of the relevant filing date was a contractual claim to enforce the royalty obligation,[15] to which the declaratory counts were anticipatorily pled[16] as defenses.[17] Other decisions, *see* n.19, *infra*,

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[15] *See Luckett v. Delpark, Inc.*, 270 U.S. 496, 502 (1926) (contractual cause of action to enforce patent royalty obligation is not created by federal law).

[16] *See Lear*, 395 U.S. at 661, 674 (royalty payment obligation may be avoided due to patent invalidity or, if the license so provides, noninfringement); *MedImmune*, 549 U.S. at 122 n.1 & 135 (noting licensee's assertion "that the contract . . . does not require the payment of royalties because the patents do not cover its products and are invalid [and unenforceable]").

[17] *See, e.g., Milprint, Inc. v. Curwood, Inc.*, 562 F.2d 418, 420-22 (7th Cir. 1977) (licensee under existing license sought declaratory judgment of invalidity and determination that no royalties were owed while refusing to pay royalties; circumstances did not indicate that "licensee's nonpayment of royalties gave it reason to fear [that] the licensor would declare a forfeiture and sue for infringement," and thus only a contractual coercive "suit to

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have found Type-1 jurisdiction to exist because, *under the facts presented*, a forward-looking patent infringement coercive claim in the event of future license termination, to which such declaratory judgment counts were anticipatorily pled as defenses,[18] could also be said to have been threatened as an alternative to a forward-looking contractual coercive claim that would be assertable absent termination.[19]

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enforce payment of royalties" could be said to be " 'impending or threatened' ") (quoting *Wycoff*, 344 U.S. at 248); *Thiokol Chem. Corp. v. Burlington Indus., Inc.*, 448 F.2d 1328, 1330-31 & n.2 (3d Cir. 1971) (licensee under existing license sought declaratory judgment of invalidity, noninfringement and determination that no royalties were owed while refusing to pay royalties; circumstances indicated that licensor had not "proposed or threatened" to "terminate the license and then move against plaintiff and its vendees as infringers," and thus only a coercive "suit by the defendants charging [the] licensee with breach of contract to pay agreed sums for the licensed use of certain patents" could be said to have been "threatened"); *Product Eng'g & Mfg., Inc. v. Barnes*, 424 F.2d 42, 43-44 (10th Cir. 1970) (licensee under existing license sought declaratory judgment of invalidity and noninfringement while refusing to pay royalties; circumstances indicated that only a contractual coercive "action to enforce payment of royalties" could be said to be "'impending or threatened'") (quoting *Wycoff*, 344 U.S. at 248).

[18] *See* 35 U.S.C. §282(b) (listing invalidity, noninfringement and unenforceability as "defenses in any action involving the validity or infringement of a patent").

[19] *See, e.g.*, *Warner-Jenkinson Co. v. Allied Chem. Corp.*, 567 F.2d 184, 186-87 (2d Cir. 1977) (licensee under existing license sought declaratory judgment of invalidity and requested court permission to breach license and begin depositing "royalty payments in escrow pendente lite" following licensor's refusal to lower royalty rate; circumstances indicated "anticipation" of two "impending" alternative coercive actions, "a contract action for royalties" and "a patent infringement action"); *C.R. Bard, Inc. v.*

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The collective teaching of these decisions is that identification of the anticipated or threatened coercive

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Schwartz, 716 F.2d 874, 878-82 (Fed. Cir. 1983) (five-judge panel) (licensee under existing license sought declaratory judgment of invalidity, unenforceability, and declaration that license agreement was void and that no royalties were due while refusing to pay royalties and thereby committing "a material breach of the agreement that . . . enabled [licensor] to terminate"; "totality of the circumstances" indicated that licensee could anticipate not only a "state court contract action" but also, "under the facts of this case, . . . an infringement suit even though the license agreement was still in effect"); *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 862-63 (Fed. Cir. 1987) (licensee under existing license sought declaratory judgment of noninfringement, unenforceability, and declaration of rights under license agreement while refusing to pay royalties as to certain products following threats by licensor to terminate license and sue for infringement; circumstances indicated that licensee could anticipate not only "a state contract action brought by a licensor to enforce a license agreement," but also "being sued for patent infringement"); *Foster v. Hallco Mfg. Co., Inc.*, 947 F.2d 469, 473-74 n.3 (Fed. Cir. 1991) (licensee under existing license sought declaratory judgment of noninfringement, invalidity, and unenforceability while refusing to pay royalties as to certain products following licensor's "overtures that it would terminate the license and sue for infringement if the royalties were not paid"; circumstances indicated that licensee could anticipate suit for patent infringement as one alternative coercive action notwithstanding fact that licensor "had not terminated the license agreement at the time [licensee] brought its declaratory judgment action"); *ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1347, 1348, 1350 (Fed. Cir. 2011) (licensee under existing license sought declaratory judgment of noninfringement and declaration of rights under license agreement after having been accused of "material breach" for outsourcing manufacturing and implicitly threatened with suit "for induced infringement"; circumstances indicated that licensee could anticipate not only a state contract action brought by licensor to enforce license agreement, but also an alternative coercive "patent infringement suit").

claims in declaratory judgment actions brought by patent licensees under an existing license turns on the "totality of the circumstances." *C.R. Bard*, 716 F.2d at 880.

i. There Was No Type-1 Jurisdiction As Of The Initial Filing Date Over Any Defensive Count Because Only A Contractual Coercive Claim Was Anticipated Or Threatened

Under the specific circumstances of this case, the only coercive claim by MFV that can reasonably be said to have been anticipated, impending, or threatened as of the filing date of the initial complaint is a contractual one asserting that because the "Accused Devices" identified pursuant to the contractual procedure fell within the scope of the "Asserted Claim[s]" identified pursuant to the same procedure, they were also within the scope of the license, and royalties were owed and should be paid over to MFV rather than being deposited into escrow.

This is so because, as explained in Section I.A.1., *supra*, the parties had established a comprehensive and contractual royalty dispute resolution mechanism that permitted nested determination of all relevant patent issues under the aegis of their agreements, and had adhered to this procedure for nearly two decades, including several years of active litigation. *See* Second Amended Complaint ¶¶ 16-18; Initial Complaint ¶¶ 16-18. This contractual procedure afforded

Medtronic special privileges that were not, or at least likely were not, possessed by other patent licensees under an existing license seeking similar declaratory relief, such as the right to escrow contested royalties, to obtain a complete or partial refund of such royalties if it prevailed in whole or in part in the declaratory litigation, and to absolve its products from the royalty obligation if MFV failed to follow specified contractual procedures. *See* Section I.A.1., *supra*.

As a result, Medtronic did not, as of the initial filing date, face the patent licensee's usual choice between, on the one hand, continuing to pay royalties while litigating its declaratory judgment action and risking inability to recoup those payments, and, on the other, ceasing to pay royalties and risking termination of the license and subsequent freestanding patent litigation entailing potentially far greater damages and injunctive relief. *Medtronic could have its cake and eat it too.* There therefore was simply no chance that Medtronic suddenly would abandon the contractual dispute resolution procedure after nearly twenty years by ceasing to pay royalties when it could resolve *the very same patent issues* within the contractual framework, and when it knew that both of the licensed patents would, in any event, expire within a year. Pet. App. 30a; Pet. Br. 13 n.6. Indeed, Medtronic's own brief confirms that "Medtronic did not wish to repudiate" the license at the time it initially filed suit. Pet. for Cert. 14 n.3. That is why, of course, its initial complaint was addressed entirely to the contractual dispute resolution mechanism, was phrased in the past and present continuous tense, and made no mention of any fear of future termination of the agreements if Medtronic were to cease payment of royalties, or any anticipation of freestanding patent litigation with exposure to damages, treble damages, or injunctive relief upon any such termination.

Consequently, on the specific and unusual facts of this case, a forward-looking patent infringement coercive action by MFV in the event of a future election to terminate the license cannot reasonably be said to have been anticipated, impending or threatened as of the initial filing date, and Type-1 federal question jurisdiction therefore cannot be established over any defensive count of the initial complaint on that basis. *See Speedco, Inc. v. Estes*, 853 F.2d 909, 912-13 (Fed. Cir. 1988) (no Type-1 jurisdiction in suit by assignee under existing assignment seeking declaration of rights with respect to assigned patent because coercive patent infringement claim would have required "a complete renouncement of the assignment" by the plaintiff assignee, and was thus highly improbable even if theoretically possible; "contract action to enforce the terms of the contract" was the only realistically "threatened" coercive action).[20]

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[20] In the three decisions overturned by this Court in *MedImmune*, 549 U.S. at 132 & n.11, the Federal Circuit assumed, with no substantive discussion, with the apparent consent of all parties, and in apparent contradiction to its own prior and subsequent opinions, *see* n.19, *supra*, that it had appellate jurisdiction under §1295(a)(1), and thus the district court must

(Continued on following page)

ii. Alternatively, There Was No Type-1 Jurisdiction As Of The Initial Filing Date Over Any Defensive Count Because A Patent Infringement Coercive Claim Was Not *Necessarily* Anticipated Or Threatened

Furthermore, even assuming, *arguendo*, that a patent infringement coercive action by MFV can reasonably be said also to have been anticipated, impending or threatened as of the filing date of the

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have had exclusive federal question jurisdiction under §1338(a), *see* Section I.B., *infra*, in suits brought by licensees under an existing license seeking a declaratory judgment of noninfringement, invalidity, unenforceability, and declaration of rights under the license agreement, even though, in each case, there was no "reasonable apprehension on the part of the declaratory judgment plaintiff," as of the relevant filing date, "that it will face an infringement suit." *See MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 964, 968-69 (Fed. Cir. 2005), *rev'd and remanded*, 549 U.S. 118 (2007); *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376, 1378-79 (Fed. Cir. 2005), *vacated and remanded*, 549 U.S. 1163 (2007); *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1378, 1380 (Fed. Cir. 2004), *overruled by MedImmune*, 549 U.S. at 132 & n.11; *see also* First Amended Complaint, *MedImmune, Inc. v. Genentech, Inc.*, No. 2:03-cv-2567 (C.D. Cal. Aug. 13, 2003), 2003 WL 25539433; Second Amended Complaint, *MedImmune, Inc. v. Centocor, Inc.*, No. 8:02cv1135 (D. Md. July 30, 2003), 2003 WL 25579553.

As this Court has explained, however, *sub silentio* "jurisdictional rulings of this sort . . . have no precedential effect." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 91 (1998); *see also Lewis v. Casey*, 518 U.S. 343, 352 n.2 (1996) ("[W]e have repeatedly held that the existence of unaddressed jurisdictional defects has no precedential effect.").

initial complaint, Type-1 jurisdiction still could not be based on any defensive count.

This Court has explained that "[f]ederal courts have regularly taken original jurisdiction over declaratory judgment suits in which, if the declaratory judgment defendant brought a coercive action to enforce its rights, that suit would *necessarily* present a federal question." *Franchise Tax Bd.*, 463 U.S. at 19 (emphasis added). The natural corollary of this observation is that no Type-1 federal question jurisdiction exists where, as here, at least one *possible* coercive action is created by state law, and thus, in at least one alternative, a federally-created coercive claim would be entirely absent. *Cf. Christianson*, 486 U.S. at 810, 813 ("[A] claim supported by alternative theories in the complaint may not form the basis for [Type-2] §1338(a) jurisdiction unless patent law is essential to each of those theories.").

This Court's decision in *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002), is fully consistent with this view of Type-1 jurisdiction. In *Holmes*, the plaintiff sought "a declaratory judgment that its products did not infringe respondent's trade dress" under the Lanham Act. *Id.*, 535 U.S. at 828. At the time the complaint was filed, the declaratory judgment defendant had already initiated an ITC action claiming patent and trade dress infringement by the declaratory judgment plaintiff, and, consequently, both a coercive action for trade dress infringement, and one for patent infringement, could reasonably be said to have been anticipated, impending or threatened. *Id.* Yet this Court concluded that the declaratory "complaint did not assert any claim arising under federal patent law." *Id.* at 830. The most logical explanation for this holding is that §1338(a) federal question jurisdiction was absent because at least one *possible* alternative coercive action was not for patent infringement, and thus such an action would not *necessarily* have been presented.[21] *See also La Chemise Lacoste v. Alligator Co.*, 506 F.2d 339, 346 (3d Cir. 1974) (no Type-1 federal question jurisdiction "where federal relief was only one of three available avenues of [coercive] litigation" by the declaratory judgment defendant, as the "'character of the threatened action' was not necessarily federal in nature") (quoting *Wycoff*, 344 U.S. at 248).[22]

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[21] *Holmes* has since been statutorily overruled on other grounds, but that amendment is irrelevant here. *See* n.23, *infra*.

[22] To be sure, the Eleventh Circuit expressly has rejected this approach to Type-1 jurisdiction, albeit without any discussion of *Holmes*. *See Household Bank v. JFS Group*, 320 F.3d 1249, 1254-59 (11th Cir. 2003). Four other Courts of Appeals also have reached results inconsistent with this approach, albeit without any explicit discussion of the issue, and, again, without any mention of *Holmes*. *See Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1472 (Fed. Cir. 1997); *Cardtoons, L.C. v. Major League Baseball Players Ass'n*, 95 F.3d 959, 964-95 (10th Cir. 1996); *Great Clips, Inc. v. Hair Cuttery of Greater Boston, L.L.C.*, 591 F.3d 32, 34-35 (1st Cir. 2010); *PHC, Inc. v. Pioneer Healthcare, Inc.*, 75 F.3d 75, 77-79 (1st Cir. 1996); and the Second and Federal Circuit cases set out in n.19, *supra*.

iii. Alternatively, The District Court Was Divested Of Type-1 Jurisdiction Over All Defensive Counts By The Time Medtronic Filed Its Second Amended Complaint After Patent Expiration

Finally, even assuming, *arguendo*, that the district court properly had exercised Type-1 jurisdiction over Medtronic's initial complaint, it was divested of that jurisdiction by the time Medtronic filed its Second Amended Complaint.

Both of the licensed patents involved in this case expired by operation of law on January 23, 2009. Pet. App. 30a; Pet. Br. 13 n.6; 35 U.S.C. §251. On that date, when its obligation to pay the royalties at issue ceased, Medtronic was still a licensee in good standing. On February 10, 2009, Medtronic filed its Second Amended Complaint, JA1 (Dkt. 108); JA40-46, which superseded all prior pleadings. *See Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 456 n.4 (2009). By that point, however, because the relevant patents had expired, a nonfrivolous forward-looking patent infringement coercive action by MFV *had become impossible*; the only coercive claim left to MFV was a backward-looking contract action to recover royalties that had been paid into escrow prior to patent expiration. As a consequence, the district court lost any Type-1 federal question jurisdiction it might originally have had. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998) (federal question jurisdiction cannot be based on "wholly insubstantial and frivolous" claim) (quotation marks omitted); *cf. Arizonans for Official English v. Arizona*, 520 U.S. 43, 67 (1997) ("To qualify as a case fit for federal-court adjudication, an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed.") (internal quotation marks omitted).

The so-called time-of-filing rule does not suggest a different result. It is true that, when "subject-matter jurisdiction [is] premised upon diversity of citizenship," this Court "measures all challenges" to diversity "against the state of facts that existed at the time of filing." *Grupo Dataflux v. Atlas Global Group, L.P.*, 541 U.S. 567, 571 (2004). The time-of-filing rule, however, is animated by concerns that parties may manipulate federal court jurisdiction by engaging in a "postfiling salvage operation." *Id.* Consequently, this Court also has held that, in non-removal federal question cases, where such concerns are not implicated, the time-of-filing rule should not reflexively be applied, and that "when a plaintiff files a complaint in federal court and then voluntarily amends the complaint, courts look to the amended complaint to determine jurisdiction." *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 473-74 & n.6 (2007).

The rationale of *Rockwell* applies to this case. Both parties knew, when the initial complaint was filed, that the two patents at issue would expire a year later, on January 23, 2009. *See* 35 U.S.C. § 251. This "state of facts" never changed, and was, indeed, beyond the parties' power to change – expiration simply came about with the passage of time. The new allegations in the Second Amended Complaint related to letters MFV had sent in 2008 identifying, pursuant to the contractual procedure, additional "Accused Devices" as falling within the scope of the "Asserted Claim[s]." *See* JA41-42 (¶¶ 23-24); Second Amended Complaint ¶¶ 26-27. Medtronic could have filed an amended complaint with allegations about these letters prior to January 23, 2009 to avoid the patent expiration issue. But it did not; the Second Amended Complaint was executed by counsel on the exact date of patent expiration, January 23, 2009, and filed thereafter. *See* Second Amended Complaint at 10. Having chosen to file a superseding pleading at the time it knew the relevant patents to have expired, Medtronic must live with the consequences of that act. *See Rockwell*, 549 U.S. at 473-74.

b. There Is Also No Type-1 Jurisdiction Over The Noninfringement Counts If Viewed As Seeking Affirmative Relief

As the preceding discussion of the parties' contractual dispute resolution mechanism shows, *see* Section I.A.1., *supra*, the noninfringement declaratory counts of Medtronic's complaints, if viewed as seeking affirmative relief, are contractual in nature – Medtronic effectively asks for a declaration that because its products do not infringe, they do not fall within the scope of the royalty payment obligation under the license. Indeed, Medtronic's own brief concedes this, stating that what Medtronic seeks is a declaration that "'the agreement does not call for royalties because [its] product does not infringe the patent.'" Pet. for Cert. 2 (quoting *MedImmune*, and then noting that "Medtronic filed just such an action"); Pet. Br. 42 n.18. Such a contractual cause of action is not created by federal law, *see Luckett v. Delpark, Inc.*, 270 U.S. 496, 502 (1926), and thus does not support Type-1 federal question jurisdiction.

4. The District Court Also Lacked Type-2 Federal Question Jurisdiction

Furthermore, neither MFV's contractual coercive claim, nor the royalty-avoiding noninfringement declaratory counts of Medtronic's complaints (if viewed as seeking affirmative relief), can sustain the exercise of Type-2 federal question jurisdiction. To the extent that the parties and the lower courts assumed otherwise, that assumption did not survive this Court's recent decision in *Gunn*.

To analyze this issue, it is helpful first to review this Court's venerable decision in *Lear*. The state court in *Lear* interpreted the license agreement as covering any product that infringed certain patent claims, undertook a conventional infringement analysis, and ultimately concluded that "when the claims of the patent are interpreted in the manner set forth above," the "record demonstrates, without substantial conflict, that Lear utilized the apparatus patented by Adkins throughout the period in question" and was thus required to pay royalties under the license.

Adkins v. Lear, Inc., 435 P.2d 321, 332, 337-41 (Cal. 1968). This Court, in turn, after quoting this conclusion, noted that "the California Supreme Court's construction of the 1955 licensing agreement is solely a matter of state law." *Lear*, 395 U.S. at 661-62. *Lear*, then, teaches that in a case such as this one, the noninfringement determination is effectively a type of case within a case, a sub-issue governed by federal law nested within a broader determination as to the scope of the license and the attendant royalty payment obligation that is ultimately governed by state law.

With the holding of *Lear* in mind, we now return to the jurisdictional analysis and *Gunn*. Type-2 "federal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 133 S.Ct. at 1065 (citing *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 313-14 (2005)).

Here, as in *Gunn*, the federal law noninfringement case-within-a-case sub-issue is both "necessarily raised" and "actually disputed," for the determination of the scope of the parties' license and the attendant royalty payment obligation, in both MFV's contractual coercive claim and the royalty-avoiding noninfringement declaratory counts (if viewed as seeking affirmative relief), turns on whether Medtronic's products do or do not infringe the licensed patents. *Id.* Yet, here, as in *Gunn*, Type-2 jurisdiction nonetheless is absent because the third and fourth *Grable* factors are not met.

As this Court emphasized in *Gunn*, "it is not enough," with respect to the third *Grable* factor, "that the federal issue be significant to the particular parties in the immediate suit; that will *always* be true when the state claim necessarily raises a disputed federal issue. . . ." *Id.* at 1066 (emphasis in original; quotation marks and alterations omitted). Rather, the substantiality inquiry focuses on "the importance of the issue to the federal system as a whole." *Id.* And here, as in *Gunn*, such system-wide importance is missing – "even assuming that a state court's case-within-a-case adjudication [of infringement or noninfringement] may be preclusive under some circumstances, the result would be limited to the parties and patents that had been before the state court. Such fact-bound and situation-specific effects are not sufficient to establish federal arising under jurisdiction." *Id.* at 1067-68 (quotation marks omitted); *see also MDS (Can.), Inc. v. Rad Source Techs., Inc.*, ___ F.3d ___, No. 11-15145, 2013 WL 3285447, at *6 (11th Cir. July 1, 2013) (per curiam) (no Type-2 federal question jurisdiction over licensee's contractual cause of action regarding scope of patent license that incorporated an infringement issue – "[i]n the light of the fact-bound nature of the question, the small likelihood that the resolution of the issue would impact future cases, and the weak interest of the government in federal adjudication of this action, we cannot conclude that the issue of patent infringement presented by [the licensee] is a 'substantial question' of federal law" under *Gunn*); *Albright v. Teas*, 106 U.S. 613, 616-18 (1883) (no Type-2 federal question jurisdiction in suit for royalties under contract simply because, in assessing scope of royalty obligation, court would have to address "incidental and collateral" issue of whether "certain goods manufactured by [the assignees] . . . embody the invention covered by the . . . [assignor's] patents"). Additionally, here, as in *Gunn*, the noninfringement case-within-a-case sub-issue also is entirely "backward-looking," as the relevant patents have expired, further bolstering the conclusion that the third *Grable* factor is not met. *Gunn*, 133 S.Ct. at 1066-67.

The fourth *Grable* requirement similarly is not satisfied in this case for essentially the same reasons as in *Gunn*. State courts have, for two centuries, been understood by this Court to have the authority to adjudicate patent license contractual disputes, even when such disputes subsumed case-within-a-case infringement sub-issues governed by federal law. *See Lear*, 395 U.S. at 661-62. Undoing this historical prerogative certainly would disrupt "the federal-state balance approved by Congress," for here, as in *Gunn*, there is "no reason to suppose that Congress – in establishing exclusive federal jurisdiction over patent cases – meant to bar" such disputes "from state courts." *Gunn*, 133 S.Ct. at 1068; *see also MDS*, 2013 WL 3285447, at *6 ("To hold that all questions of patent infringement are substantial questions of federal law for the purposes of federal patent jurisdiction would sweep a number of state-law claims into federal court.").

Consequently, the district court also lacked Type-2 federal question jurisdiction.

B. The Federal Circuit Lacked Appellate Jurisdiction

The version of section 1295(a)(1) applicable to this case[23] bases the Federal Circuit's appellate jurisdiction on the existence of section 1338(a) jurisdiction in the district court. *See Christianson*, 486 U.S. at 807. Thus, because the district court, as demonstrated in Section I.A., *supra*, lacked subject-matter jurisdiction under section 1338(a), the Federal Circuit lacked appellate jurisdiction under section 1295(a)(1). Consequently, the Federal Circuit's judgment should be vacated, and the case remanded with instructions to transfer the appeal to the Third Circuit pursuant to 28 U.S.C. §1631 to determine whether another jurisdictional basis in the district court, such as diversity, existed, and to decide the appeal on the merits if it did. *See Christianson*, 486 U.S. at 819.

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[23] Section 1295(a)(1) was amended, for actions filed on or after September 16, 2011, to overrule this Court's decision in *Holmes*. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 19(b), (e), 125 Stat. 284, 331-33 (2011). That amendment is irrelevant here.

II. ALTERNATIVELY, VACATUR AND REMAND ARE APPROPRIATE BECAUSE THE BURDEN OF PERSUASION IN THIS CASE MAY BE GOVERNED BY STATE, NOT FEDERAL, LAW

Even assuming, *arguendo*, that Type-2 exclusive federal question jurisdiction properly was invoked in this case, vacatur and remand nonetheless are appropriate for another, independent, reason. The parties and the courts below assumed that the burden of persuasion issue was governed by federal law. As the following discussion shows, that is not necessarily the case.

A. The Burden Of Persuasion As To The Scope Of A Patent License, Even One Defined In Terms Of Noninfringement, Is Ordinarily A Matter Of State Law

Vertical-choice-of-law analysis is a matter entirely independent of the basis for the federal courts' subject-matter jurisdiction. *See, e.g., O'Melveny & Myers v. F.D.I.C.*, 512 U.S. 79, 85 (1994) (undertaking vertical-choice-of-law analysis and holding that state law governed issue in case where subject-matter jurisdiction was conferred by federal statute, 12 U.S.C. §1819(b)(2)).[24] Consequently, even assuming

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[24] *See also* 19 Charles A. Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice and Procedure §4520 at 635 (2d ed. 1996 & Supp. 2013) ("[I]t is the *source* of the right sued upon, and not the ground on which federal jurisdiction over

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the presence of Type-2 jurisdiction, the vertical-choice-of-law issue remains.

As discussed in Section I.A.4., *supra*, this Court has held that when the coverage of a patent license is defined in terms of noninfringement of the licensed patents, the noninfringement determination is a type of case within a case, a sub-issue governed by federal law nested within a broader determination as to the scope of the license and the attendant royalty payment obligation that is ultimately governed by state law. *See Lear*, 395 U.S. at 661-62.

Additionally, this Court consistently has held that the burden of persuasion is substantive for vertical-choice-of-law purposes, and thus, if a state rule of decision governs a particular issue, the burden of persuasion on that issue also is defined by state law. *See Raleigh v. Ill. Dep't of Revenue*, 530 U.S. 15, 20-21 (2000) ("Given its importance to the outcome of cases, we have long held the burden of proof to be a 'substantive' aspect of a claim.").[25]

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the case is founded, which determines the governing law.") (emphasis in original, quotation marks omitted).

[25] *See also Dick v. N.Y. Life Ins. Co.*, 359 U.S. 437, 446 (1959) ("Under the *Erie* rule, presumptions (and their effects) and burden of proof are 'substantive'. . . ."); *Palmer v. Hoffman*, 318 U.S. 109, 117 (1943) (burden of persuasion is "a question of local law"); *Cities Serv. Oil Co. v. Dunlap*, 308 U.S. 208, 212 (1939) (burden of persuasion entailed "a substantial right," and was governed "by the local rule.").

Combining these two premises, it follows that the ultimate burden of persuasion on whether certain products fall within the scope of a patent license, and thus incur a royalty payment obligation, *presumptively* must also be a matter of state law – even when the scope of that license is defined in terms of a nested noninfringement issue that must, case-within-a-case fashion, be analyzed under federal law.

Why presumptively? Because one further matter must be considered. *Lear* explains that a state rule of decision otherwise applicable to patent licenses must give way to a federal common law rule in those rare situations where the application of state law would work "a substantial impairment of overriding federal policy." *Lear*, 395 U.S. at 673. As this Court's recent decision in *Gunn* makes clear, however, no such "overriding federal policy" is at work here.

In *Gunn*, the case-within-a-case issue was one of patent invalidity. *See Gunn*, 133 S.Ct. at 1062-63. In ordinary patent infringement litigation, invalidity is an affirmative defense on which the accused infringer bears the burden of persuasion as a matter of statutory command. *See* 35 U.S.C. §282(a). Yet this Court was entirely untroubled by the fact that, in the state-law-based malpractice action, it was the *patentee* who would have to bear the burden of persuasion on this issue, and would have to show that his patent would have been found *valid*. *See Gunn*, 133 S.Ct. at 1065 ("To prevail on his legal malpractice claim, therefore, Minton must show that he would have prevailed in his federal patent infringement case if only petitioners had timely made an experimental-use argument on his behalf.").

If no overriding federal policy in *Gunn* required displacement of the state-law-imposed reversal of the burden of persuasion on invalidity, even in the face of the statutory command of section 282(a), then, *a fortiori*, no such overriding federal policy exists in this case, given the absence of any generally-applicable statute governing the burden of persuasion on the issue of infringement in ordinary patent litigation.[26] Consequently, the default rule remains – the ultimate burden of persuasion as to whether certain products fall within the scope of a patent license, and thus incur a royalty payment obligation, ordinarily is a matter of state law.

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[26] Indeed, the only statute that has anything to say on the matter requires the *accused infringer* to prove *noninfringement* under certain circumstances in ordinary patent litigation. *See* 35 U.S.C. §295 (under recited conditions, "the burden of establishing that the product was not made by the [patented] process shall be on the party asserting that it was not so made."); *Nutrinova Nutrition Specialties & Food Ingredients GmbH v. Int'l Trade Comm'n*, 224 F.3d 1356, 1359-60 (Fed. Cir. 2000) (Section 295 "requires the alleged infringer to disprove infringement."). *But see* Pet. Br. 37-38 (omitting key statutory language from quotation and arguing that section 295 merely shifts burden of production).

B. Remand Is Necessary To Determine If The Parties Contracted Out Of The Default Rule, And, If Not, What State Law Provides

In this case, however, the default rule is not the final word, because the parties' agreements contain potentially applicable choice-of-law clauses.

The 1991 License provides, in relevant part, that "[a]ll matters affecting the interpretation, form, validity, and performance of The Agreement shall be decided under the laws of the state of Minnesota, including its procedural laws. . . ." JA14. Thus, in the agreement that initially provided for a declaratory judgment action by Medtronic in which it could, while maintaining its license, seek a determination that no royalties were owed because a particular product did not infringe a licensed patent, the parties did not purport to contract out of the default rule, other than to specify that Minnesota law governed.

The 2006 Litigation Tolling Agreement, however, while restating the declaratory judgment action provisions, altered the choice-of-law clause to read that "[t]his Agreement shall be interpreted and construed, and the legal relations created herein shall be determined, in accordance with the laws of the State of Minnesota *and the United States*." JA29 (emphasis added).

The lower courts in this case – in addition to not acknowledging the default choice-of-law rule on the burden of persuasion – never addressed the question of whether the inclusion of federal law in the choice-of-law clause in this latter agreement was intended by the parties to alter that default rule. Consequently, vacatur and remand are necessary for the lower courts to consider, in the first instance, whether the parties contracted out of the default choice-of-law rule on the burden of persuasion, and, if they did not, what the allocation of the burden of persuasion would be in this case under Minnesota law. *See O'Melveny*, 512 U.S. at 89 (declining to decide, in the first instance, issue of state law not addressed by lower courts, and remanding for decision on that issue).

* * *

A final thought. Parties choose to define the scope of patent licenses in a wide variety of ways. Some licenses, like the one at issue here, focus on infringement of the licensed patents; others on a particular contractual definition of the licensed technology. Pet. Br. 42 n.18. If the Court is inclined to reach the merits and create a federal common law rule of decision on the burden of persuasion issue, it should carefully limit that rule to licenses where the scope is defined in terms of infringement and that, like the one here, specifically contemplate declaratory litigation of patent issues by the licensee under the aegis of the agreement. Other types of licenses present issues that have not been briefed and argued.

CONCLUSION

For the foregoing reasons, the Federal Circuit's judgment should be vacated, and the case remanded with instructions to transfer the appeal to the Third Circuit. Alternatively, the case should be remanded for consideration of the vertical-choice-of-law issue on the allocation of the burden of persuasion.

Respectfully submitted,

RENEE DUBORD BROWN
TESSERA TECHNOLOGIES, INC.

ROMAN MELNIK*
Counsel of Record
KENNETH WEATHERWAX
NATHAN N. LOWENSTEIN
FLAVIO M. ROSE†
GOLDBERG, LOWENSTEIN
& WEATHERWAX LLP

*Also Lecturer in Law
USC GOULD SCHOOL OF LAW
699 Exposition Blvd.
Los Angeles, CA 90089

†Also Corporate
IP Attorney
BANDGAP ENGINEERING, INC.
6 Gill St., Unit H
Woburn, MA 01801

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Counsel for Amicus Curiae Tessera Technologies, Inc.